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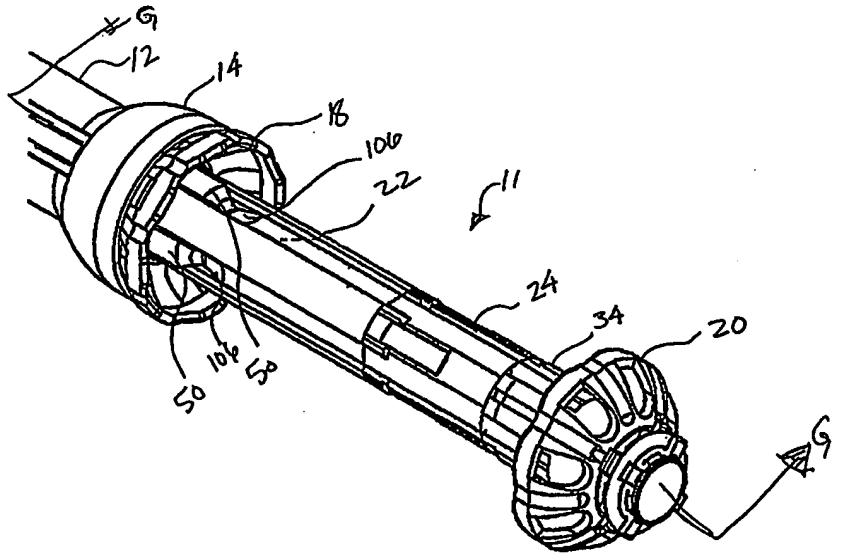
(54) Title: TRANSANAL ANASTOMOSIS RING INSERTION DEVICE

(57) Abstract

The invention relates to a device for transanally inserting through the lower bowel one of two unitary members of a Biofragmentable Anastomosis Ring (BAR). The device comprises a curved shaft with a handle and an actuating knob at the proximal end, a nest formed at the distal end of the shaft adapted to mount a BAR carrier assembly, and a second passageway formed through the shaft that terminates at a distal open end formed through the nest. The BAR carrier assembly includes unitary male and female members that collectively comprise the BAR, male and female carriers for mounting the respective unitary member, and a collet for locking in and releasing the BAR from the BAR carrier assembly once both unitary members are secured to respective open ends of the upper and lower bowel section. The BAR Carrier Assembly is actuatable in one of three positions: open, closed, and released. Once secured to the upper bowel section, the surgeon attaches the male carrier with its attached male member to the BAR Carrier Assembly, thus placing the Assembly in the open position. The surgeon then places the BAR Carrier Assembly in the closed position by mating the male member to the female member seated in the nest. Once in the closed position, the surgeon places the BAR Carrier Assembly in the released position by actuating the insertion device and releasing the mated unitary members of the BAR from the BAR Carrier Assembly and withdrawing the insertion device from the lower bowel.



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TRANSANAL ANASTOMOSIS RING INSERTION DEVICE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention generally relates to a surgical device, and more particularly to an anastomosis ring insertion device for use in anastomosing tubular body organs in connection with, for example, intestinal surgery.

2. Prior Art

After a surgical procedure, such as cutting and removing a diseased or cancerous portion of the bowel, the severed ends of the bowel must be anastomosed or rejoined. Several procedures are available for anastomosing two sections of hollow tubular body organs, such as the intestines. Known procedures for anastomosing two sections of hollow tubular body organs together include suturing, stapling or clamping the severed ends together. For example, U.S. Patent Nos. 4,576,167, No. 4,603,693 and No. 4,646,745 are directed to anastomosis procedures utilizing circular surgical staplers for anastomosing two hollow body organs.

Another procedure uses anastomosis buttons and clamps to join two sections of hollow body organs together. U.S. Patent Nos. 3,771,526, No. 4,055,186 and No. 4,154,241 are exemplary of such anastomosis devices. The devices disclosed in these patents utilize inserter rods which are forced upwardly into the rectum through the anus in order to position one half of a clamp device in the lower colon and engage the other half of the clamp device positioned in the upper colon, so as to draw and join the two hollow body organ halves together.

Still another procedure involves use of an anastomotic device that is the subject of U.S. Patent Nos. 4,467,804, No. 4,467,804 and No. 4,766,898, which are assigned to the

assignee of the present invention, and marketed and sold under the VALTRAC® trademark. The anastomotic device disclosed under these patents receives the open ends of intestines to be purse stringed and anastomosed over and between a pair of ring members that comprise the VALTRAC®. The ring members have mechanical connecting means which mate with each other in order produce secure serosa-to-serosa apposition of the neds of the instestines and maintains a satisfactory patency unitl healing occurs and the ring members degrade into small harmless fragments which are eliminated from the body. The ring members, also referred to collectively as a Biofragmentable Anastomosis Ring (BAR), are formed of a bio-absorbable material that permits disintegration of the BAR in a relatively short period of time after healing of the intestines begins, thereby eliminating the need for metal staples and clamps which do not disintegrate and pass through the patient's system. Acceptable materials for manufacturing the BAR are disclosed in U.S. Patent No. 3,297,033 and include, but are not limited to, poly-hydroxy acetic ester and lactate copolymers which are herein incorporated by reference. However, use of this type of anastomotic device requires that the surgeon work solely through an abdominal opening made in the patient, which is disadvantageous when performing anastomosis to the lower bowel due to the limited space available in the pelvic area for performing such a procedure.

U.S. Patent No. 5,464,415 discloses a sutureless anastomosis gun for a BAR for use in sutureless ansatomosis of the intestine near the anus. The anastomosis device disclosed in this patent drives an inner sleeve and a ring seat by means of nut and screw rod arrangement such that the end of the rectum is pushed precisely to enter the gap of the BAR and then the BAR is exactly closed about the portion of the intestines to be anastomosed. Thereafter, the ring seat and the BAR are disengaged and the anastomosis gun

removed from the rectum. However, the anastomosis gun of this type does not transanally insert one member of the BAR so that an exact closing about the portion of the intestines to be anastomosed is not required.

U.S. Patent Nos. 4,667,673 and 5,282,810, also assigned to the assignee of the present invention, disclose an anastomosis applicator device for mounting the BAR and a method for inserting the applicator and BAR transanally. The device includes a mounting extension for mounting the two halves of the BAR and an inserter which is curved and adapted for transanal insertion. The inserter portion of the applicator passes through the interior of the rectum and out through the exterior of the anus so that the placement of the BAR can be done without the difficulty present in having to access the lower bowel area solely through the pelvic area.

However, it is desirable that further improvements to the transanal applicator be made related to better mounting and application of the device during an anastomosis procedure.

OBJECTS AND SUMMARY OF THE INVENTION

A principle object of the present invention is to provide an applicator insertion device for surgically inserting a BAR.

It is a further object of the present invention to provide an insertion device for surgically inserting a unitary member of a BAR in an open end of the lower bowel through the anal orifice.

It is another object of the present invention to provide an insertion device for surgically inserting a unitary member of a BAR in an open end of the upper bowel through an abdominal insertion.

It is still a further object of the present invention to provide an insertion device that swiftly and easily

mounts, closes, and releases both unitary members of the BAR in order to clamp the open ends of the bowel in a contiguous manner.

These and other objects of the present invention are realized in a presently preferred embodiment thereof, described by way of example and necessarily by way of limitation, which provides for an insertion device for transanally inserting one of two unitary members of a BAR through the rectum and securing it to the open end of the lower bowel, while inserting the other unitary member through an abdominal opening and securing it to the open end of the upper bowel. The insertion device of the present invention comprises a curved shaft with a handle and knob at the proximal end, a nest formed at the distal end thereof adapted to mount a BAR carrier assembly, and communicating first and second passageways formed through the shaft which terminate at a distal end opening formed through the nest.

The BAR carrier assembly includes unitary male and female members that collectively comprise the BAR, male and female carriers for temporarily mounting both unitary members of the BAR onto the insertion device, a protective cover for safe and comfortable transanal insertion of the insertion device, and a collet/drawbar arrangement for locking in and releasing the BAR from the BAR Carrier Assembly once both unitary members are secured to respective open ends of the upper and lower bowel and then mated together prior to release. In the preferred embodiment, both unitary male and female members include a plurality of openings interposed between scallops in juxtaposition relationship which are formed through the dome of each unitary member. The openings promote the fragmentation of the BAR after a period of time by allowing the BAR to break down into smaller pieces when it begins to disintegrate, thereby allowing the fragments to more easily pass out the body through the stool. The scallops which form the outer edge of each unitary member form a continuous bumpy pattern

thereabout that serves to better clamp the open ends of the bowel between the two unitary members of the BAR when mated together, thereby promoting vascularity of healthy bowel tissue during anastomosis.

The knob positioned at the proximal end of the shaft communicates with a threaded body that includes a threaded channel adapted to engage a rod member connected to a flexible shaft member. Formed or attached thereto at the distal end of the shaft member is a drawbar adapted to engage the connectors of the collet. The collet has a body having a distal end that includes an elongated stem with a wedge formed at the free end thereof while a plurality of connectors at the opposite end of the collet body extend generally axially therefrom.

Both male and female carriers have hollow generally tubular bodies with opposed proximal and distal openings, respectively. The proximal opening of the male carrier includes a concentric pattern of connectors adapted for attachment to the distal opening of the female carrier while the distal opening of the male carrier forms a plurality of generally axially extending legs with retaining jaws formed at the free end thereof.

During manufacturing, the female carrier and female member are pre-loaded to the distal end of the insertion device by engaging the female carrier to the shaft and inserting the female carrier through the aperture formed through the dome of the female member. Mating prongs formed on the female member then engage slots formed on the female carrier, thereby seating the female carrier securely in the nest of the insertion device. Further, the collet is pre-loaded to the male carrier by inserting the collet through the male carrier so that the wedge of the collet is placed between the plurality of legs, thereby biasing apart the legs. Prior to inserting the collet through the male carrier, the male member is pre-loaded to the distal end of the male carrier so that the retaining jaw formed at the

free end of each leg of the carrier is advanced through the aperture formed in the dome of male member. Once the legs are advanced through the aperture of the male member so that the retaining jaws engage the peripheral area around the aperture, the wedge of the collet is then inserted through the male carrier until the bump formed opposite of each retaining jaw engages a retaining ridge formed around the circumference of the wedge and biases apart the plurality of legs. A biasing means, for example a garter spring, is received around the inside of each retaining jaw so as to provide a counter force that locks the wedge of the collet between the legs of the male carrier, thereby locking the male member to the distal end of the male carrier.

In operation, a surgeon makes an abdominal opening through an incision made in the patient in order to access the bowel area. The surgeon then severs the bowel into an upper bowel section and a lower bowel section and then cleans the edges of each respective bowel section of any cancerous or diseased portion in order to ensure healthy tissue is present for anastomosis. The pre-loaded male member with the male carrier attached thereto is then inserted through the abdominal opening by the surgeon and the edge of the upper bowel section is secured around the outer edge of the male member in a contiguous manner thereto by employing, for example a purse string stitch pattern, using a absorbable suture material to secure the edge of the upper bowel section. After the upper bowel section is secured, the surgeon inserts the distal end of the shaft, with the pre-loaded female member attached thereto, through the rectum of the patient and into the bowel until the shaft appears through the lumen of the lower bowel section.

Once the shaft has been inserted through the lower bowel, the edge of the lower bowel section is secured around the outer edge of the female member in a manner similar to the securement of the upper bowel section to the male member. Upon securing both upper and lower bowel sections,

the surgeon attaches the male carrier with its connected male member to the distal end of the female carrier, so as to place the BAR Carrier Assembly in the open position with the female member spaced apart from the male member along the axis of the Carrier Assembly. Further, when the male carrier is attached to the female carrier, the collet engages the drawbar so that the collet can release the male member at the appropriate time when the device is actuated.

Once the BAR Carrier Assembly is in the open position, the surgeon actuates the device in order to place the Carrier Assembly in the closed position and mate the male member to the female member. In order to actuate the device and place the BAR Carrier Assembly in the closed position, the surgeon rotates the knob of the device between the thumb and forefinger in a clockwise direction, which causes the male and female carriers to be pulled into the second passageway of the shaft due to the drawbar's engagement with the collet. As both carriers are pulled into the second passageway by the drawbar, the male member is brought to mating engagement with the female member seated in the nest of the shaft, thereby placing the BAR Carrier Assembly in the closed position.

During the mating sequence between the male member and the female member, the mating prongs of the female member engage respective slots formed in the tubular member of the male member in such a manner as to maintain contiguous contact between the opposing portions of the upper and lower bowel sections secured to the outer edge of each respective unitary member. Once the two unitary members are mated and both sections of the bowel secured, the surgeon places the BAR Carrier Assembly in the release position by rotating the knob in a counter-clockwise direction. This counter-clockwise rotation causes the drawbar to move in an axial direction away from the knob, thereby causing the collet to move forward relative to the male carrier. The relative forward movement of the collet also removes the wedge from

between the plurality of legs of the male carrier and releases the mated unitary members of the BAR from the BAR Carrier Assembly. Once release of the BAR has been effected, the surgeon withdraws the shaft of the device from the lower bowel section of the patient and the procedure is completed.

In an alternative embodiment, the proximal end of the collet has a cross bar-like configuration similar to the one formed at the distal end of the drawbar in the preferred embodiment, while the alternative drawbar has a plurality of connectors similar to those formed at the proximal end of the collet body in the preferred embodiment. The alternative embodiment, with the exception of the collet and drawbar, is structurally and operatively the same as the preferred embodiment.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of the anastomotic device according to the present invention;

FIG. **2** is a partial cross-section view of the shaft and handle of the anastomotic device shown in FIG. **1** according to the present invention;

FIG. **3** is an exploded view of the distal end of the anastomotic device illustrating the various components of the BAR Carrier Assembly according to the present invention;

FIG. **4** is a side view of the male member according to the present invention;

FIG. **5** is a cross-section view of the male member shown in FIG. **4** along lines **A-A** according to the present invention;

FIG. **6** is a perspective view of the male member shown in FIG. **4** according to the present invention;

FIG. **7** is a top view of the male member shown in FIG. **4** according to the present invention;

FIG. **8** is a side view of the female member according to

the present invention;

FIG. **9** is a cross-section view of the female member shown in FIG. **8** along lines **B-B** according to the present invention;

FIG. **10** is a top view of female member shown in FIG. **8** according to the present invention;

FIG. **11** is a perspective view of the female member shown in FIG. **8** according to the present invention;

FIG. **12** is a side view of the male carrier according to the present invention;

FIG. **13** is a cross-section view of the male carrier shown in FIG. **12** along lines **C-C** according to the present invention;

FIG. **14** is a perspective view of the male carrier shown in FIG. **12** according to the present invention;

FIG. **15** is an end view of the male carrier shown in FIG. **12** according to the present invention;

FIG. **16** is a side view of the collet according to the present invention;

FIG. **17** is a cross-section view of the collet shown in FIG. **16** along lines **D-D** according to the present invention;

FIG. **18** is a perspective view of the collet shown in FIG. **16** according to the present invention;

FIG. **19** is a side view of the female carrier according to the present invention;

FIG. **20** is a cross-section view of the female carrier shown in FIG. **19** along lines **E-E** according to the present invention;

FIG. **21** is a perspective view of the female carrier shown in FIG. **19** according to the present invention;

FIG. **22** is an end view of the female carrier shown in FIG. **19** according to the present invention;

FIG. **23** is a side view of the distal end of the shaft according to the present invention;

FIG. **24** is a cross-section view of the distal end of

the shaft shown in FIG. **23** along lines **F-F** showing the nest and second passageway according to the present invention;

FIG. **25** is an end view of the distal end of the shaft shown in FIG. **23** according to the present invention;

FIG. **26** is a perspective view of the drawbar according to the present invention;

FIG. **27** is an end view of the drawbar shown in FIG. **26** according to the present invention;

FIG. **28** is a perspective view of the distal end of the shaft illustrating the BAR Carrier Assembly in the open position;

FIG. **29** is a cross-section view of the distal end of the shaft and BAR Carrier Assembly shown in FIG. **28** along lines **G-G** according to the present invention;

FIG. **30** is a perspective view of the distal end of the shaft illustrating the BAR Carrier Assembly in the closed position;

FIG. **31** is a cross-section view of the distal end of the shaft and BAR Carrier Assembly shown in FIG. **30** along lines **I-I** according to the present invention;

FIGS. **31A-31C** illustrate the mating sequence between the male member and the female member when the BAR Carrier Assembly is being placed in the closed position shown in FIG. **31** according to the present invention;

FIG. **32** is a perspective view of the distal end of the shaft illustrating the BAR Carrier Assembly in the released position according to the present invention;

FIG. **33** is a cross-section view of the distal end of the shaft and BAR Carrier Assembly shown in FIG. **32** along lines **J-J** according to the present invention;

FIG. **34** is a perspective view of the protective showing the preferred embodiment according to the present invention;

FIG. **35** is a perspective view showing an alternative embodiment of the protective cover according to the present invention.

FIG. **36** is a perspective view showing an alternative embodiment of the collet according to the present invention;

FIG. **37** is a side view of the collet shown in FIG. **36** according to the present invention;

FIG. **38** is a perspective view showing an alternative embodiment of the drawbar according to the present invention;

FIG. **39** is an end view of the drawbar shown in FIG. **38** according to the present invention;

FIG. **40** is a cross-section view of the drawbar shown in FIG. **38** along lines **K-K** according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings, the preferred embodiment of the anastomosis device of the present invention is illustrated and generally indicated as **10** in FIG. **1**. As shown in FIG. **1**, the anastomosis device **10** comprises a curved elongated shaft **12** integrally attached to or formed with a handle **13** at its proximal end, while a BAR carrier assembly **11** is attachable to distal end of shaft **12**. Referring to FIG. **2** a partial cross-section showing the interior of the anastomosis device **10** is illustrated. Handle **13** forms a hollow tubular configuration having connected first and second passageways **43** and **45**, respectively, that extend axially therethrough from a first opening **31** formed at the proximal end of anastomosis device **10** through the shaft **12** where the second passageway **45** terminates at a second opening **33** formed at the distal end thereof. The first passageway **43** extends axially from the first opening through the handle **13** where it communicates with the smaller diameter second passageway **45** where the handle **13** meets the shaft **12**.

Preferably, shaft **12** comprises a two-part assembly that includes first and second identical halves **65** and **67** (FIG.

25) that are attached together by pins (not shown) inserted and secured through holes **41** formed through the body of shaft **12**. Although the preferred embodiment discloses a pin and hole arrangement for securing first and second halves **65** and **67** together, it is within the scope of the present invention that halves **65** and **67** can be attached by other securing means to include, but not limited to, adhesive bonding, tongue and groove arrangement, riveting or other suitable means of attachment. Preferably, shaft **12** and handle **13** are made from a hard plastic material or any kind of material suitable for injection molding. However, in the alternative, metal may also be used to manufacture the shaft **12** and handle **13**.

A window **17** (FIG. **1**) is formed through handle **13** for providing a visual indication to the surgeon as to the state of closure of the BAR Carrier Assembly. A color mark or other visual indicator (not shown), such as a notch, is provided on a rod member **23** that is seen through window **17** when anastomosis device **10** is actuated and the BAR Carrier Assembly **11** is being placed in the closed position. The state of closure is determined by how much mark **10** fills window **17**, with full closure having mark **10** filling the entire window **17**.

A knob **15** having a gripping surface adapted for secure gripping between a user's thumb and forefinger is provided for actuating anastomosis device **10** from an open to a closed position, and finally to a release position. Knob **15** further includes an annular-shaped threaded body **21** with an undercut **39** interposed therebetween. The threaded body **21** is disposed in the first passageway **43** and forms an internal axial threaded channel **29** therethrough that includes a series of threads (not shown) adapted for engagement to rod member **23**. The distal end of first passageway **43** has a lip **37** adapted for engagement to undercut **39**, so that threaded body **21** is retained inside passageway **43** while permitting

body **21** to freely rotate therein. Rod member **23** also has a series of threads formed around the outer surface thereof that mate and engage the threads of threaded body **21** when the proximal end of rod member **23** is inserted into the threaded channel **29** during assembly of the anastomosis device **10**. Rotation of knob **15** in a clockwise direction rotates threaded body **21** so that rod member **23** is pulled axially toward knob **15** while rotation of knob **15** in a counter-clockwise direction extends the rod member **23** away from knob **15**. Although the preferred embodiment of the present invention discloses a clockwise rotation of knob **15** for axially pulling in rod member **23** and a counter-clockwise rotation for axially extending away member **23**, it is within the scope of the present invention that rotation of knob **15** can be in either direction for pulling in or extending out member **23**.

Integrally attached to or formed with the distal end of rod member **25** is a flexible shaft member **25** that extends through the portion of the second passageway **45** that is formed through shaft **12**. A plurality of channeling members **27** are strategically located at points along the top and bottom portions of second passageway **45** for guiding the shaft member **25** along passageway **45** during its back-and-forth motion as the anastomosis device **10** is actuated, as shall be explained in greater detail later. The shaft member **25** is preferably a flat strip integrally attached to or formed with a cross-shaped drawbar **16** at the free end thereof. Drawbar **16** is adapted for engagement to the BAR carrier assembly **11** that is attachable to the distal end of anastomosis device **10**.

Referring to FIG. **3**, an exploded view of the distal end of the anastomosis device **10** and its attachable BAR carrier assembly **11** is shown. The BAR carrier assembly **11** comprises a BAR **19** that includes a female member **18** and a male member

20 that mate together to form a unitary biofragmentable anastomosis ring. As shall be discussed in greater detail later, female member 18 engages a female carrier 22 by inserting the carrier 22 through an aperture 54 formed through the female member 18. Female carrier 22 has a hollow generally tubular shape with open ends and is adapted for engagement with shaft 12 when the proximal end of the carrier 22 is inserted into the second passageway 45. A male carrier 24, also forming a hollow generally tubular body with open ends and a plurality of legs 60 formed at the distal end thereof, is attachable to the female carrier 22 when the BAR Carrier Assembly 11 is placed in the open position. During manufacturing, a collet 28 is pre-loaded to the male carrier 24 and male member 20 and is provided for locking and subsequently releasing the wedge 84 of collet 28 from between the plurality of legs 60 of carrier 24 when collet 28 is inserted into the hollow generally tubular body of the male carrier 24 and through the plurality of legs 60. Prior to locking wedge 84 between the plurality of legs 60, legs 60 are inserted through the aperture 32 of male member 20 and engaged to the peripheral area around aperture 32, so that when wedge 84 is inserted through legs 60 and biases apart legs 60, the male member 20 is effectively locked to the male member 20. A biasing means 26, for example an O-ring or garter spring, is provided around the free end of the plurality of legs 60 for applying a counter-biasing force that locks against wedge 84 between the plurality of legs 60 and pre-loads the male member 20 to the male carrier 24, as shall be explained in greater detail later.

Besides both male and female members 18 and 20, BAR carrier assembly 11 further comprises respective female and male carriers 22 and 24 and collet 28 and is attachable to the distal end of shaft 12. The distal end of shaft 12 forms an annular nest 14 where the second opening 33

communicates with the second passageway **45** formed inside shaft **12**. Nest **14** has a dome-like shape that forms a receptacle adapted for seating the dome-side of the female member **18**. Extending axially from the second opening **33** is drawbar **16**. As shall be explained in greater detail below, drawbar **16** is inserted through an aperture **54** formed in the center of the female member **18** that is seated in nest **14**, and is designed to engage and retain the BAR Carrier Assembly **11** to the shaft **12**.

Referring to FIGS. **4-7**, the male member **20** is illustrated in greater detail. Male member **20** includes a dome **30** with an aperture **32** formed in center thereof, while a concentric pattern of openings **53** are in juxtaposition between scallops **55** formed around the exterior surface of dome **30**. Each opening **53** forms a bullet shaped aperture through dome **30** while each scallop **55** cuts a small arc along the outer edge **49** between each opening **53**. Dome **30** further includes an interior cavity **40** having an outer edge **49** which surrounds a tubular member **34** that extends axially from the aperture **54** through cavity **40**. A portion of the exterior surface of tubular member **34** forms a plurality of axially extending ring raceways **36** which are equally spaced around the circumference of member **34**. These ring raceways **36** are shallow channels extending axially along the exterior surface of tubular member **34** from the free end thereof to a point approximately halfway up member **34** where each raceway **36** terminates forming a slot **38** that communicates with the interior area of member **34**. The interior area of tubular member **34** forms a ring channel **46** that includes a series of axially extending grooves **42** spaced equally around the circumference of the interior surface thereof and formed between the protruding shallow channels of the ring raceways **36**.

Referring to FIGS. **8-11**, the female member **18** is shown

in greater detail. Female member **18** includes a concentric-shaped dome **48** similar configuration to dome **30** of male member **20** and has an interior cavity **56** having an outer edge **58** and an inner edge **57** that forms an axial aperture **54** in the center of dome **48**. Dome **48** further includes the same pattern of openings **53** and scallops **55** found on male member **20**, which form a similar concentric pattern as disclosed above. Extending axially from the inner edge **57** of aperture **54** and into the interior of cavity **56** are a plurality of mating prongs **50** with a pawl **52** formed at the free end of each prong **50**. Each pawl **52** forms a protruding portion adapted for engagement with a respective slot **36** of the male member **20** when the female member **18** is mated thereto. The leading edge of each pawl **52** is angled in order to provide a tunneling action that tunnels under and clears any obstruction, for example a severed bowel section, that might obstruct any one of the raceways **36** during mating of the male member **20** to the female member **18**.

Referring to FIGS. **12-15**, the male carrier **24** is shown in greater detail. Male carrier **24** comprises a carrier body **70** having a hollow generally tubular shape that forms a carrier channel **76** with opposing distal and proximal open ends **59** and **61**. The distal open end **59** forms the plurality of generally axially extending legs **60** that are spaced equally around the circumference of open end **59** and set at a slight inward angle thereto. The free end of each leg **60** forms retaining jaws **64** having upper and lower jaws **66** and **68**, respectively. The upper and lower jaws **66** and **68** form a pocket adapted to receive a biasing means **26**, for example a resilient O-ring or garter spring, for biasing the plurality of legs **60** together, however any type of resilient biasing means is felt to fall within the scope of the present invention. Opposite each upper jaw **66** is a bump **63** adapted to engage and retain wedge **84** of collet **28**, as shall be

explained in greater detail later. The carrier body **70** further includes a plurality of axially extending slots **62** spaced equally around the circumference of the proximal open end **61** in juxtaposition relation between each first carrier raceway **72**. Each first carrier raceway **72** forms an exterior shallow channel adapted for engaging and guiding the prongs **50** toward mating engagement with the male member **20** when the BAR Carrier Assembly is placed in the closed position. Provided at the proximal end of male carrier **24** are a plurality of connecting members **74** spaced equally around the circumference of the male carrier channel **76** at the entrance thereof and in axial alignment with the slots **62**. Connecting members **74** are adapted for engagement with connection slots **104** of female carrier **22** when male carrier **24** is connected thereto.

Referring to FIGS. **16-18**, collet **28** is shown in greater detail. Collet **28** serves as part of the release mechanism when the BAR **19** is being released from the BAR carrier assembly **11** and comprises first and second generally identical halves **94** and **96**, respectively, as illustrated in FIG. **18**. Preferably, the two halves **94** and **96** are attached to one another by tongue and groove arrangement strengthened by adhesive bonding, although any other suitable means of attachment, such as, but not limited to ultrasonic welding, riveting or a combination of any of the above, is felt to fall within the scope of the present invention. Each halve **94** and **96** includes opposing tongue **81** and **83** and groove **85** and **87** arrangements, respectively, for properly orienting and connecting the two halves **94** and **96** together by inserting the tongue **81** of halve **94** into the groove **85** formed in halve **96**. Conversely, the tongue **83** of halve **96** is inserted into the groove **87** formed in halve **94** when the two halves **94** and **96** are attached prior to bonding the two halves **94** and **96** together in a unitary structure using a suitable adhesive.

The proximal end of the collet body **80** includes a plurality of prongs **86** with a connector **88** formed at the free end of each respective prong **86**. The connectors **88** are adapted for engagement with the drawbar **16** while the distal end of the collet body **80** forms an elongated stem **82** having a wedge **84** at the free end thereof. The wedge **84** has a truncated conic section and a retaining ridge **100** formed around the upper section of wedge **84** adapted for retaining bump **63** of legs **60**. As shall be explained in greater detail later, the wedge **84** forms a part of the release mechanism that locks in as well as releases the BAR **19** during use of the anastomosis device **10**.

Referring to FIGS. **19-22**, the female carrier **22** is shown in greater detail. Female carrier **22** includes a carrier body **108** that has a generally hollow tubular shape with opposing proximal and distal open ends **105** and **107**. Formed through the carrier body **108** are opposing retaining windows **102** adapted for engagement with the shaft **12** when the female carrier **22** is inserted thereto. A means for guiding the female member **18** axially along the exterior surface of female carrier **22** is provided in the form of a pair of opposing second carrier raceways **112**. Second carrier raceways **112** comprise exterior shallow channels adapted for engaging and guiding the four mating prongs **50** of the female member **18** along the female carrier **22** until the prongs **50** engage retaining slots **106** formed at the mid point of each respective raceway **112**.

Distal open end **107** forms an annular opening that includes a plurality of connection slots **104** spaced equally around the circumference thereof, which are adapted for connection to a respective connecting member **74** of male carrier **24**. The connection slots **104** have beveled surfaces that facilitate engagement with the connection members **74** in a loose attachment fit thereto. Distal open end **107** forms

one end of female carrier channel **110** that communicates through the hollow tubular configuration of female carrier **22** to the proximal opening **105**.

Referring to FIGS. **23-25**, the distal end of shaft **12** is shown in greater detail. Shaft **12** comprises two identical halves **65** and **67** that are preferably injection molded and attached to one another by adhesive bonding or other suitable means of attachment. As noted above, the nest **14** includes a flared cup-shaped receptacle **128** having the distal opening **89** formed in the center therethrough which communicates with second passageway **45**. Spaced apart from distal opening **89** of shaft **12** along the surface thereof are opposed shaft windows **120** that each form respective opposing retaining fingers **118**. Each retaining finger **118** includes a tang **122** at the free end thereof. Each tang **122** has a protruding portion **123** adapted to engage a respective retaining window **102** when the proximal open end **105** of female carrier **22** is inserted into the second passageway **45** through nest **14**. As illustrated in FIGS. **24** and **25**, second passageway **45** forms an axial channel with a plurality of guides **130** equally spaced around the circumference thereof for guiding the proximal open end **105** of the female carrier **22** into the passageway **45**. The guides **130** are adapted to engage the respective second carrier raceway **112** of female carrier **22** so that the carrier **22** slides into the second passageway **45** until the tangs **122** of the retention fingers **118** engage the retaining window **102** of female carrier **22**, thereby retaining the proximal open end **105** of the female carrier **22** inside shaft **12** while the distal open end **107** thereof extends out from passageway **45**.

As the female carrier **22** is inserted into second passageway **45**, the drawbar **16** disposed therein is concurrently inserted through the female carrier channel **110** of female carrier **22**. Drawbar **16** forms a cross-bar

configuration having first, second, third and fourth axial channels **148**, **150**, **152** and **154** that extend the length of drawbar **16**. In order to engage the connectors **88** of collet **28**, the free end of drawbar **16** includes a cross bar **132** having four wings **134** with beveled edges adapted to engage the connectors **88** and prevent disengagement therefrom when drawbar **16** is pulled into second passageway **45**, as shall be discussed in greater detail below. Spaced apart from cross bar **132** along drawbar **16** and positioned in each channel **148**, **150**, **152** and **154** is a stop **124** provided for preventing the connectors **88** of collet **28** from being inserted too far down the drawbar **16** when the collet **28** is engaged thereto.

During manufacturing, collet **38** is pre-loaded to the male carrier **24** by inserting collet **28** through male carrier **24** so that the wedge **84** of collet **28** is placed between the plurality of legs **60** of carrier **24**, thereby biasing apart the legs **60**. Prior to inserting collet **28** through male carrier **24**, male member **20** is attached to the distal end of the male carrier **24**, so that each retaining jaw **64** formed at the free end of each leg **60** is advanced through aperture **32** formed in dome **30** of male member **20**. Once plurality of legs **60** are advanced through aperture **32** so that the retaining jaws **64** engage the peripheral area around the aperture **32**, the wedge **84** of collet **28** is then inserted through the carrier channel **76** of male carrier **24** until the retaining ridge **100** formed around the circumference of wedge **84** engages bump **63** formed opposite of each retaining jaw **64**, thereby biasing apart legs **60**. A biasing means **26**, for example a garter spring, is received inside each retaining jaw **64** so as to provide a counter force that locks the wedge **84** between the legs **60**, thereby locking the male member **20** to the distal open end **59** of male carrier **24**.

Referring to FIGS. **28-35**, the method for using the anastomosis device **10** will be discussed. During a surgical

procedure for joining two severed halves of hollow body organs, such as intestines, the proximal open end **105** of female carrier **22** is inserted into the second passageway **45** of shaft **12** until the retaining fingers **118** engage the retaining windows **102** of shaft **12**, thereby pre-loading the carrier **22** to shaft **12**. Once the female carrier **22** is pre-loaded to the shaft **12**, carrier **22** is inserted through the aperture **54** of female member **18** until the dome **48** thereof is seated in nest **14**. Once the female member **18** is seated a protective cover **138** is inserted over the distal open end **107** of female carrier **22** in order to protect the patient during insertion of the anastomosis device **10** through the rectum.

FIG. **34** shows the preferred embodiment of the protective cover **138**. Cover **138** comprises a cover body **140** having a bullet- shaped configuration that forms an interior cavity **140** with an opening **144** adapted to receive and retaining the distal open end **107** of female carrier **22**. A plurality of axially extending retaining guides **146** are formed on the interior surface of cavity **140** for guiding the distal end of female carrier **22** and retaining carrier **22** therein. FIG. **35** shows an alternative embodiment of the protective cover **138**, designated **238**, is similar to the preferred embodiment discussed above except the cover **238** includes a cover body **254** that has a plurality of scallops **256** formed on the exterior surface thereof to assist the user in gripping the cover **238**.

In a surgical procedure to anastomosis two hollow body organs together, the surgeon first makes an abdominal opening by making an incision in the abdominal area of a patient in order to access the bowel region. The surgeon then severs the diseased portion of the bowel into a lower and an upper bowel sections (not shown), respectively, and cleans the respective edges of the severed bowel of any remaining diseased portions in order to ensure that only

healthy tissue is to be anastomosed. Once the free ends of each bowel section have been cleaned, the surgeon inserts the pre-loaded male carrier **24** through the abdominal opening and secures the free end of the upper bowel section around the outer edge **49** of male member **20** in a contiguous manner using a purse string stitch that utilizes suitable absorbable sutures known in the art such as, but not limited to coated or uncoated polyglycolic acid suture. Once the upper bowel section has been secured, the surgeon inserts the distal end of shaft **12** of anastomosis device **10** into the rectum and through the bowel region until the distal end of shaft **12** appears through the lumen of the lower bowel section. The surgeon then secures the free end of the lower bowel section around the outer edge **55** of female member **18** using the same purse string stitch as described above.

After the lower bowel section is properly secured to the female member **18**, the surgeon attaches the male carrier **24** to the female carrier **22** already attached to the drawbar **16** of shaft **12**. The attachment of the two carriers **22** and **24** is accomplished by engaging the connecting members **74** of the male carrier **24** to the connecting slots **104** of female carrier **22** in secure engagement thereto, thereby placing the BAR carrier assembly **11** in the open position, as illustrated in FIGS. **28** and **29**. Further, when male carrier **24** is attached to the female carrier **22**, the connectors **88** of collet **28** have already been attached to cross bar **132** of drawbar **16**, so that the collet **28** can release the male member **20** at the appropriate time when the device **10** is actuated and drawbar **16** is extended axially away from shaft **12** in order to release the female member **18** and male member **20** from the BAR Carrier Assembly **11**, as shall be discussed in greater detail below.

Referring to FIGS. **30** and **31** , the closed position of the BAR carrier assembly is shown. After the male member **20** is locked to the BAR carrier assembly **11** by collet **28** and is

placed in the open position, the surgeon then actuates anastomosis device **10** so as to place the assembly **11** in the closed position and mate the male member **20** to the female member **18**. In order to place the BAR carrier assembly **11** in the closed position, the surgeon rotates the knob **15** in a clockwise direction, thereby rotating the rod member **23** in an axial direction toward knob **15**. This axial movement of the rod member **23** toward knob **15**, releases the female carrier **22** from engagement with retaining fingers **118** of shaft **12**, so that the carrier **22** and male carrier **24** are pulled into the second passageway **45** of the anastomosis device. This movement of the carriers **22** and **24** into the second passageway **45** concurrently causes the male member **20**, which is attached to the male carrier **24**, to move towards, and eventually mate with, the female member **18**.

Referring to FIG **31**, a cross-section view of the male member **20** fully mated to the female member **18** with the BAR carrier assembly **11** in the closed position is illustrated. As the male carrier **24** is pulled into the second passageway **45**, the pawl **52** of each mating prong **50** of female member **18** eventually engages the respective slot **38** formed in the tubular member **34** of the male member **18**, thereby mating the two members **18** and **20** in a unitary structure.

Referring to FIGS. **31A-31C**, the mating sequence between the female and male members **18** and **20** is illustrated. In FIG. **31A** the prongs **52** of female member **18** engage the ring raceway **36** of the tubular member **34** of male member **20** as the two members **18** and **20** begin to mate. FIG. **31B** illustrates the prongs **52** beginning to engage the slots **38** of male member **20** while FIG. **31C** shows the prongs **52** fully inserted into the slots **38** and the two unitary members **18** and **20** fully mated.

Referring to FIGS. **32** and **33**, the BAR carrier assembly **11** is shown in the release position. Once the unitary

members **18** and **20** are mated, the surgeon rotates knob **15** in a counter-clockwise direction so that the drawbar **16** moves in an axial direction away from knob **15**. As the drawbar **16**, which is engaged to the prongs **86** of the collet **28**, moves axially, the wedge **84** is concurrently removed from between the legs **60** of male carrier **24**, thereby causing the legs **60** to collapse toward each other as the biasing means **26** forces the legs **60** inward and releases the BAR **19**.

Referring to FIGS.**40** and **41**, an alternative embodiment of collet **28** is shown and generally designated as **328**. Collet **328** is of unitary manufacture and comprises a collet body **380** that includes a drawbar portion **392** formed at one end and a wedge **384** formed at the other end thereof. The drawbar portion **392** includes first, second, third and fourth axial channels **383**, **385**, **387** and **389** that extend axially along portion **392** and terminate at crossbar **397**. Cross bar **397** has a generally cross-bar configuration that forms first, second, third and fourth wings **370**, **371**, **372**, and **373**, respectively, at the free end of drawbar **316**. Each wing **370**, **371**, **372**, and **373** in combination with an adjacent wing **370**, **371**, **372**, or **373** forms an axially extending wing channel **399** that forms at the free end of drawbar portion **392** and tapers down to a respective channel **383**, **385**, **387** and **389**.

The collet body **380** further comprises a middle portion **396** of generally tubular cross section that is interposed between drawbar portion **392** and a front portion **394**. Front portion **394** has a conical member **395** that meets a stem **382** and terminates with a wedge **384** formed at the free end thereof. Wedge **384** is of similar construction as wedge **84** and is used in the similar lock and release arrangement described in the preferred embodiment.

Referring to FIGS. **38-40**, an alternative embodiment of drawbar **16** is shown and generally designated as **316**. Drawbar

316 comprises to identical halves 315 and 317 which are attached to each other by adhesive bonding or other suitable means of attachment. Each wing 370, 371, 372, and 373 of crossbar 397 is adapted for engagement with drawbar 316. Drawbar 315 includes a proximal end 321 and a distal end 322. As seen in FIG. 43, proximal end 321 includes a pair rounded ends 313 with a slot 319 formed therebetween and a channel 324 that extends through the proximal end 321 in traverse relation to the axis of drawbar 316. Slot 319 extends vertically between the pair of rounded edges 313 and is adapted to receive the free end of shaft member 25. Preferably, shaft member 25 also includes an opening (not shown) that aligns with opening 324 when member 25 is attached to the proximal end 321 of drawbar 316. A pin (not shown) is then inserted through the entire channel 324 and engaged thereto by means well known in the art so that shaft member 25 is secured to the drawbar 316. Alternatively, other means of securing shaft member 25 to the proximal end 321 of drawbar 316 that fall within the scope of the present invention include, but are not limited to, a snap fit attachment, riveting or tongue and groove engagement.

Distal end 322 of drawbar 316 forms a plurality of axially extending connectors 320 that extend away from the free end thereof. Connectors 320 are of similar construction as the connectors 88 disclosed in the preferred embodiment of the collet 28 and are adapted for similar engagement with the drawbar portion 392 of collet 328 when the male carrier 24 is attached to the female carrier 22 by the surgeon when placing the BAR Carrier Assembly in the open position. The construction and structure of the other portions of the insertion device 10 remain unchanged.

It should be understood from the foregoing that, while particular embodiments of the invention have been illustrated and described, various modifications can be made thereto without departing from the spirit and scope of the

invention. Therefore, it is not intended that the invention be limited by the specification; instead, the scope of the present invention is intended to be limited only by the appended claims.

CLAIMS

We Claim:

1. A medical device for use in joining of free ends of two tubular members comprising:

first and second ring members, said first and second ring members being securable to a respective free end of each tubular member to be anastomosed,

an insertion member having a distal end and a proximal end, said insertion device adapted for transanally inserting one of said ring members so that said ring member extends through one of the free ends of the tubular members,

a carrier assembly attachable to said distal end of said insertion device, said carrier assembly including first and second carriers for attachment and release of said first and second ring members, said first carrier being attachable to said distal end of insertion device and said second carrier being attachable to said first carrier, said first and second ring members being positionable at first and second predetermined distances from each other.

2. The medical device according to claim 1, wherein said first and second ring members each comprise a dome, each of said domes further comprising an inner periphery that forms an aperture and an outer periphery that forms an outer edge.

3. The medical device according to claim 1, wherein each of said respective domes further forms an interior cavity

4. The medical device according to claim 1, wherein said first and second ring members are positionable in opposed relation to one another.

5. The medical device according to claim 3, wherein said first and second ring members are positionable in opposed

relation to one another so that said interior cavities of each of said respective dome faces the other.

6. The medical device according to claim 1, wherein when said first and second ring members are positioned at said first predetermined distance, said carrier assembly is in an open position.

7. The medical device according to claim 1, wherein when said first and second ring members are positioned at said second predetermined distance, said carrier assembly is in a closed position.

8. The medical device according to claim 1, wherein when said first and second ring members are positioned at said second predetermined distance, the respective secured free end of each of the tubular members are in contiguous contact with the other tubular member in an anastomotic state.

9. The medical device according to claim 7, wherein said first carrier comprises a hollow tubular body forming a channel therethrough having distal and proximal open ends thereof, said distal end forming a plurality of axially extending legs, said first carrier further comprising a plurality of axially extending first raceways formed along an exterior of said first carrier, said first raceways adapted for guiding one of said first ring member toward said second member when said carrier assembly is placed in the closed position.

10. The medical device according to claim 9, wherein said second carrier comprises a hollow tubular body forming a channel therethrough having distal and proximal open ends thereof, said second carrier further comprises a plurality of axially extending second raceways formed along an exterior surface thereof, said second raceways adapted for

guiding the said first ring member towards the second ring member when said carrier assembly is placed in the closed position.

11. The medical device according to claim 9, wherein each of said plurality of legs forms a pair of jaws at the free end thereof.

12. The medical device according to claim 11, wherein each said pair of jaws is adapted to receive a biasing means such that said plurality of legs are biased towards each other by said biasing means.

13. The medical device according to claim 12, wherein said biasing means is a garter spring.

14. The medical device according to claim 12, wherein said biasing means is an O-ring.

15. The medical device according to claim 1, which further comprises a lock and release for locking said first ring member to said first carrier and subsequently releasing said first and second ring members from said carrier assembly after said first and second ring members have been placed in said second predetermined distance from one another.

16. The medical device according to claim 15, wherein said lock and release comprises a collet body having a proximal end and a distal end, said distal end of said collet body including an elongated stem with a wedge formed at the free end thereof.

17. The medical device according to claim 16, wherein said collet body is adapted for insertion through said proximal open end of said first carrier such that said wedge biases apart said plurality of legs.

18. The medical device according to claim 17, wherein said first ring member is locked in place to said distal open end of said first carrier by placement of said plurality of legs through said aperture of said first ring member and placement of said wedge of said collet body between said plurality of legs, thereby forcing apart said plurality of legs by the presence of said wedge while said biasing means simultaneously applies a counter force that locks said plurality of legs against said wedge.

19. The medical device according to claim 18, wherein said proximal end of said insertion member includes an actuator, said actuator being capable of effecting the release of said first ring member from said first carrier by moving said wedge in an axial direction from between said plurality of legs such that said biasing means collapses said plurality of legs in the absence of said wedge and releases said first and second ring members.

20. The medical device according to claim 10, wherein when said first and second ring members are positioned at said first predetermined distance, said carrier assembly is placed in said open position

21. The medical device according to claim 10, wherein when said first and second ring members are positioned at said second predetermined distance, said carrier assembly is placed in said closed position,

22. The medical device according to claim 21, wherein when said carrier assembly is placed in said closed position, said first ring member is mated to said second ring member in such a manner as to collectively form a sphere-like shape with a slot formed along the equator, said slot adapted for receiving thereabout said secured free ends of said tubular member in a contiguous manner.

23. The medical device according to claim 22, wherein said first ring member is mated to said second ring member by guiding said first ring member axially towards said second ring member along said first and second raceways, respectively.

24. The medical device according to claim 19, wherein said actuator includes a rotatable knob.

25. The medical device according to claim 2, wherein said dome includes a plurality of openings therethrough.

26. The medical device according to claim 2, wherein said inner periphery of each of said first and second members forms a bumpy pattern adapted for gripping the secured free ends of the tubular member therebetween.

27. The medical device according to claim 16, wherein said insertion member comprises an actuator, said actuator being operably connected to a shaft member, said shaft member including a drawbar for operably engaging said proximal end of said collet body in order to release of the mated first and second ring members.

28. The medical device according to claim 26, wherein said insertion member further comprises a shaft at said distal end thereof and a handle formed at the proximal end thereof.

29. The medical device according to claim 28, wherein said handle forms a window, said window giving a visual indication of the state of actuation of said carrier assembly.

30. The medical device according to claim 28, wherein said visual indication of the state of actuation is a color mark.

31. The medical device according to claim 28, wherein said visual indication of the state of actuation is a notch formed through said shaft member, said notch providing said visual indication of the state of actuation by the percentage of said notch that is visible through said window.

32. The medical device according to claim 10, wherein when said carrier assembly is placed in said closed position, said actuator operates to axially pull in said second carrier through said distal open end of said shaft until said first carrier is received into said distal open end, thereby mating said first and second ring members.

33. The medical device according to claim 23, wherein said distal end of said insertion device forms a nest, said nest adapted to receive said second ring member thereto.

34. The medical device according to claim 32, wherein when said first and second ring members are mated, said second member is disposed in said nest and said first ring member is driven axially towards said second ring member along said first and second carriers until said first ring member mates with said second ring member.

35. An anastomotic device for use in joining of free ends of two tubular members to be anastomosed comprising:

first and second ring members, said first and second ring members being securable to a respective free end of each tubular member to be anastomosed,

an insertion member having a distal end and a proximal end, said insertion device adapted for transanally inserting one of said ring members so that said ring member extends through one of the free ends of the tubular members,

a carrier assembly attachable to said distal end of said insertion device, said carrier assembly including first and second carriers for attachment and release of said first and second ring members, said first carrier being attachable to said distal end of insertion device and said second carrier being attachable to said first carrier, said first and second ring members being positionable at first and second predetermined distances from each other along the axis of said carrier assembly and then being releasable from said carrier assembly.

36. An anastomotic device for use in joining free ends of an upper tubular section and a lower tubular section to be anastomosed comprising:

first and second ring members, said first and second ring members being securable to a respective free end of each tubular member to be anastomosed,

an insertion member having a distal end and a proximal end, said insertion device adapted for transanally inserting one of said ring members so that said ring member extends through one of the free ends of the tubular members,

a carrier assembly attachable to said distal end of said insertion device, said carrier assembly including first and second carriers for attachment and release of said first and second ring members, said first carrier being attachable to said distal end of insertion device and said second carrier being attachable to said first carrier, said first and second ring members being positionable in opposed relation to one another at first and second predetermined distances from each other along the axis of said carrier assembly and then being releasable from said carrier assembly

37. A method for anastomosing free ends of an upper tubular member and a lower tubular member using an anastomotic device comprising first and second ring members, said first

and second ring members being securable to the respective free end of the upper and lower tubular members to be anastomosed, an insertion member having a distal end and a proximal end, said insertion device adapted for transanally inserting one of said ring members so that said ring member extends through one of the free ends of the tubular members, a carrier assembly attachable to said distal end of said insertion device, said carrier assembly including first and second carriers for attachment and release of said first and second ring members, said first carrier being attachable to said distal end of insertion device and said second carrier being attachable to said first carrier, said first and second ring members being positionable at first and second predetermined distances from each other, the method comprising the steps of:

a) making an abdominal opening in a patient so as to expose a region of the bowel that requires surgery;

b) severing the region of the bowel into upper and lower tubular members, each of the upper and lower tubular members forming respective open free ends;

c) inserting the first ring member with the first carrier attached thereto through the abdominal opening and securing the upper tubular member around the first ring member;

d) inserting the insertion device into the rectum and through the region of the bowel with the second ring member and the second carrier attached to the distal end of the insertion device, the insertion device being inserted through the region of the bowel until said distal end appears through the free end of the lower tubular member, the distal end of the insertion device being covered by a protective cover;

e) removing the protective cover from the distal end of the insertion device;

f) securing the lower tubular member around the second ring member;

g) attaching the first carrier to the second carrier, thereby placing the first and second ring members at the first predetermined position;

h) actuating the insertion device, thereby placing the first and second ring members at the second predetermined position;

i) further actuating said insertion member, thereby effecting release of the first and second ring members from the insertion device; and

j) removing the insertion device from the region of the bowel and rectum and closing the abdominal opening.

38. The method according to claim 37, wherein the respective first and second ring members further comprise first and second domes, respectively, said first and second domes each forming an inner periphery and an outer periphery, said step of securing the lower tubular member to the first ring member further comprises securing the free end of the lower tubular member around the outer periphery of said first dome in a contiguous manner.

39. The method according to claim 38, wherein said step of securing the upper tubular member to the second ring member further comprises securing the free end of the upper tubular member around the outer periphery of said second dome in a contiguous manner.

40. The method according to claim 36, wherein said step of actuating the insertion device comprises rotating an actuator disposed at the proximal end of the insertion device in a clockwise direction so as to bring the first ring member towards mating engagement with the second ring member.

41. The method according to claim 36, wherein said step of further actuating the insertion device comprises further

rotating said actuator until the mated first and second ring members are released from said insertion device.

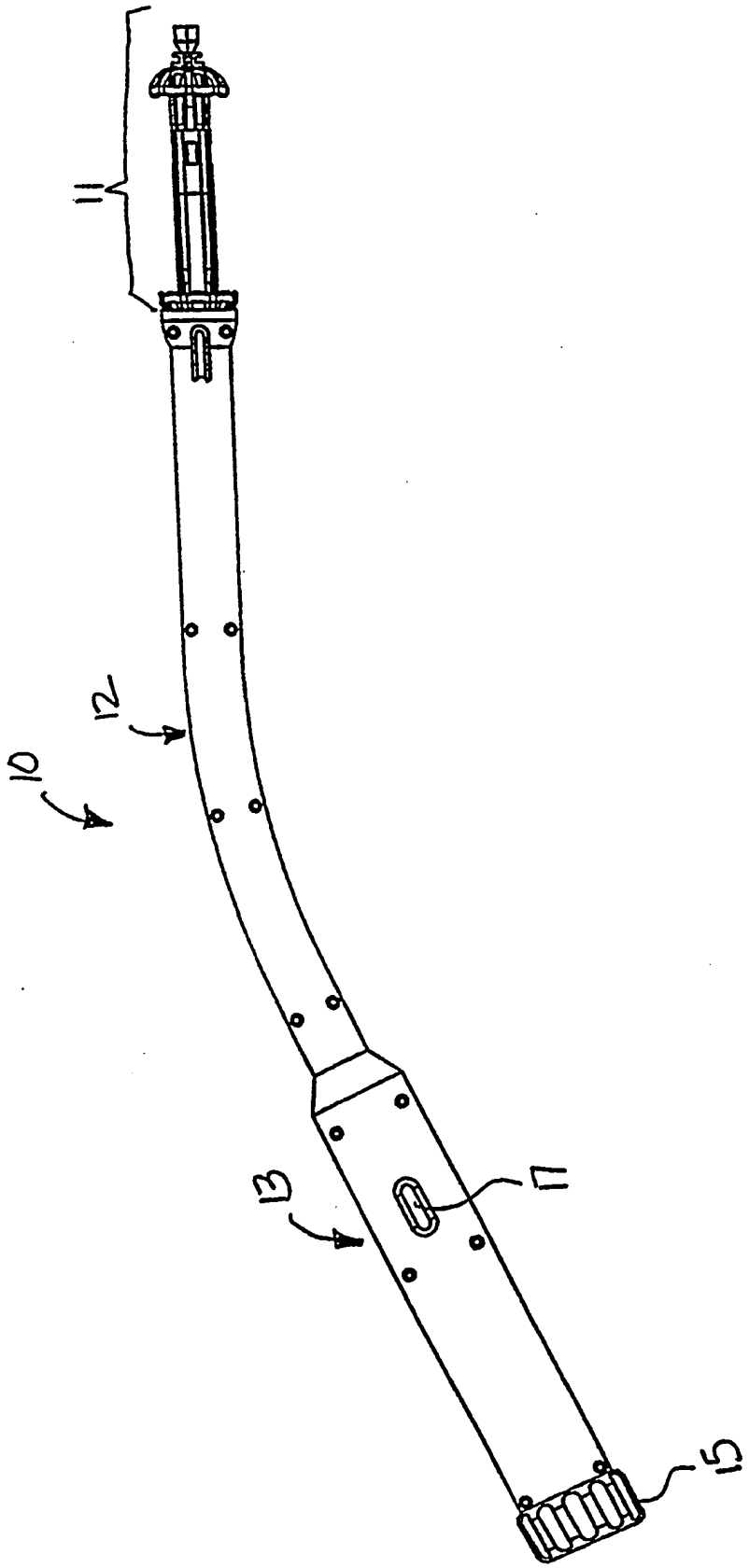

FIG. 1

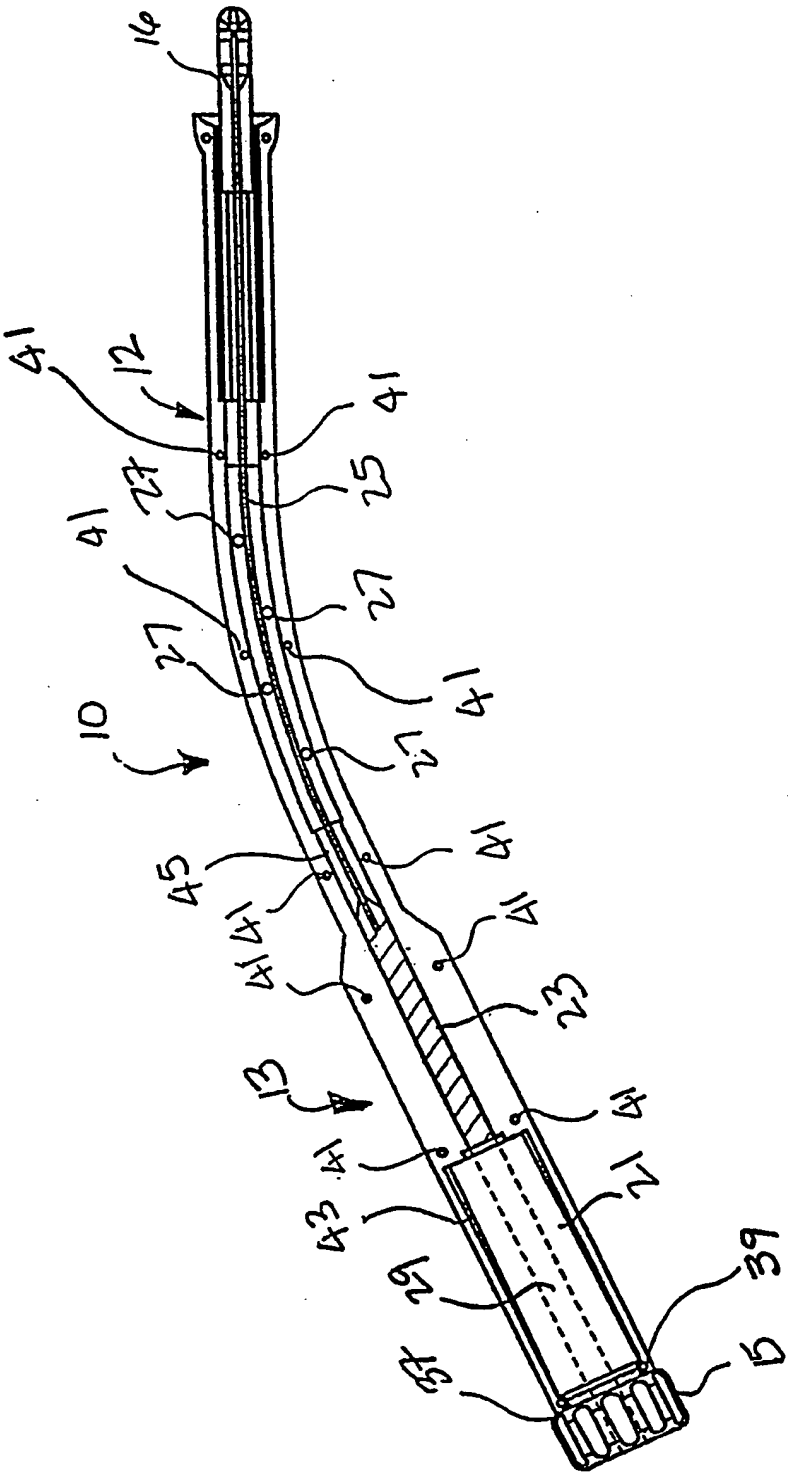
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FIG. 2

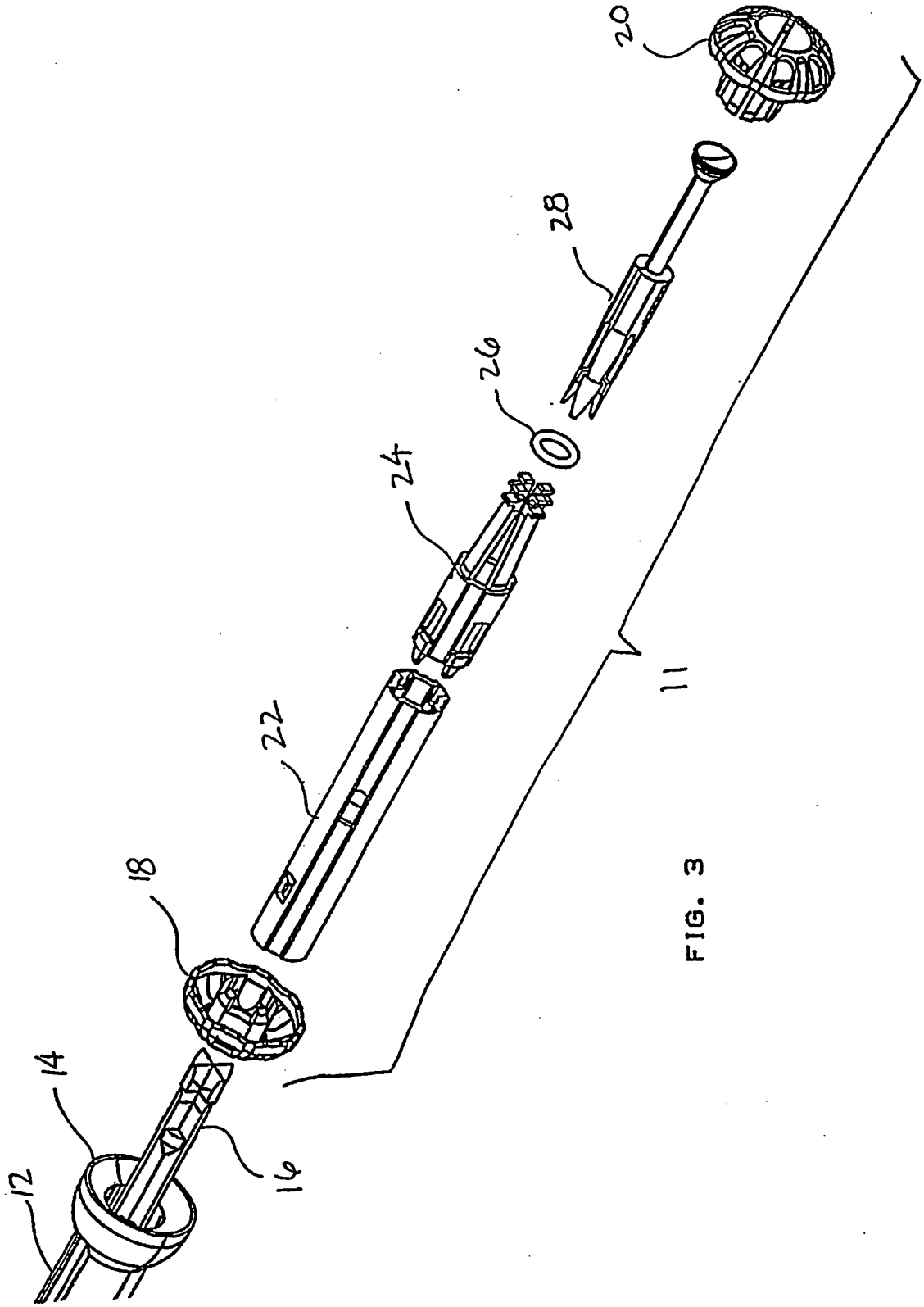


FIG. 3

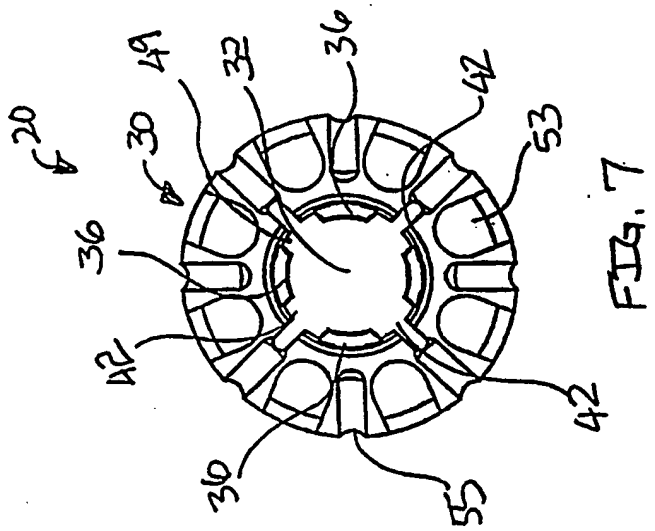
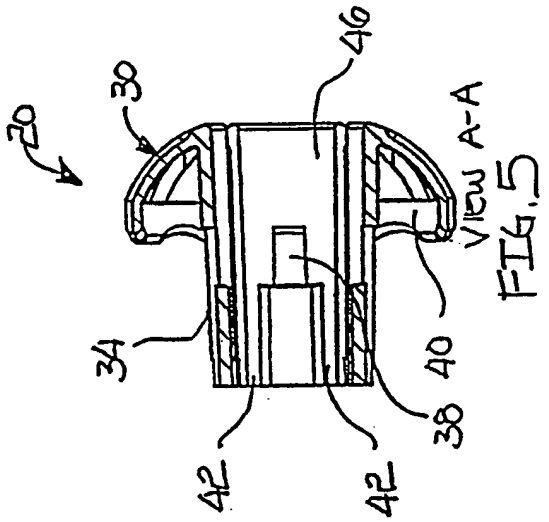


FIG. 7



VIEW A-A

FIG. 5

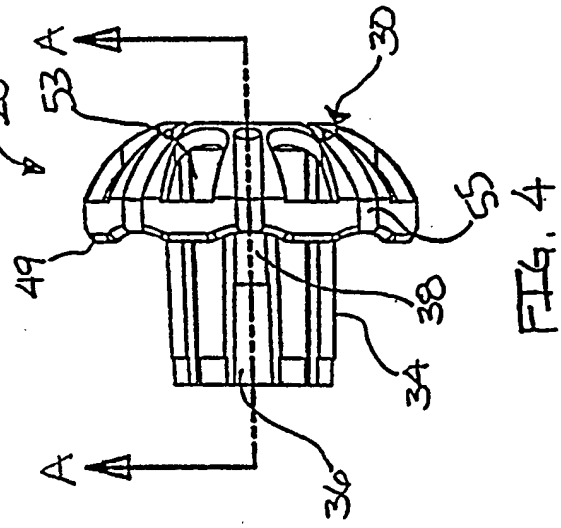


FIG. 4

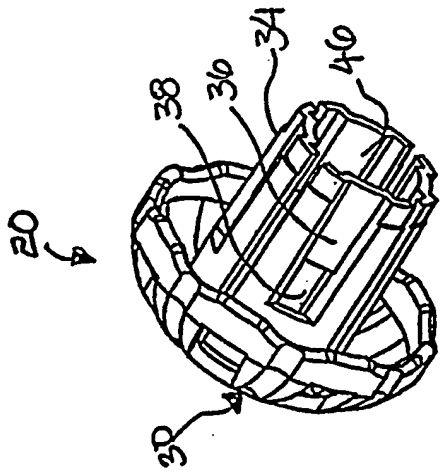


FIG. 6

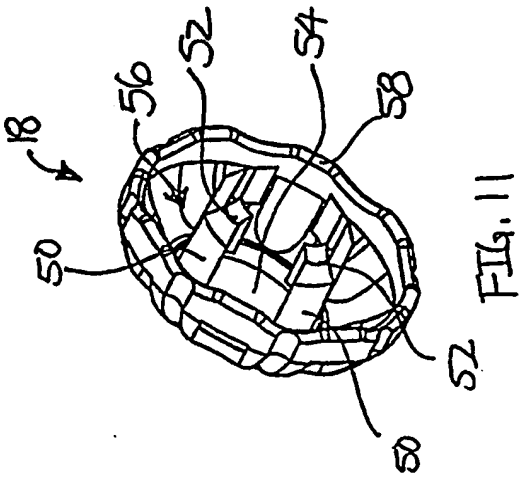


FIG. 11

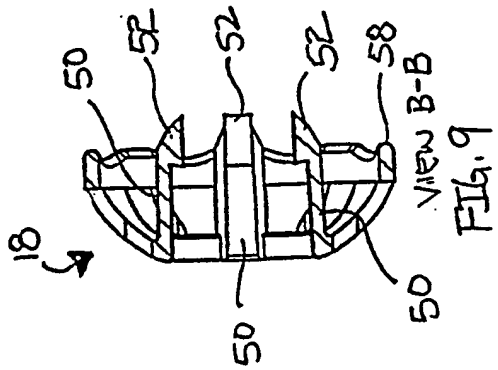


FIG. 9

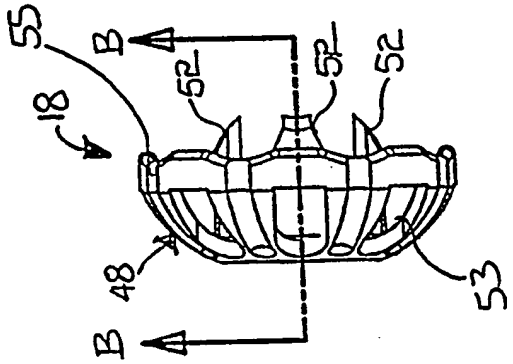


FIG. 8

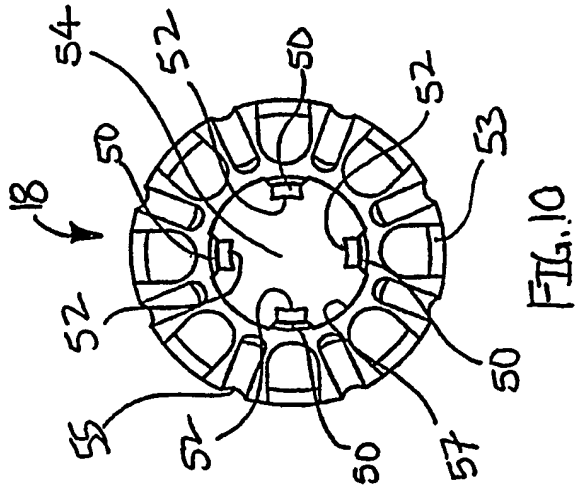


FIG. 10

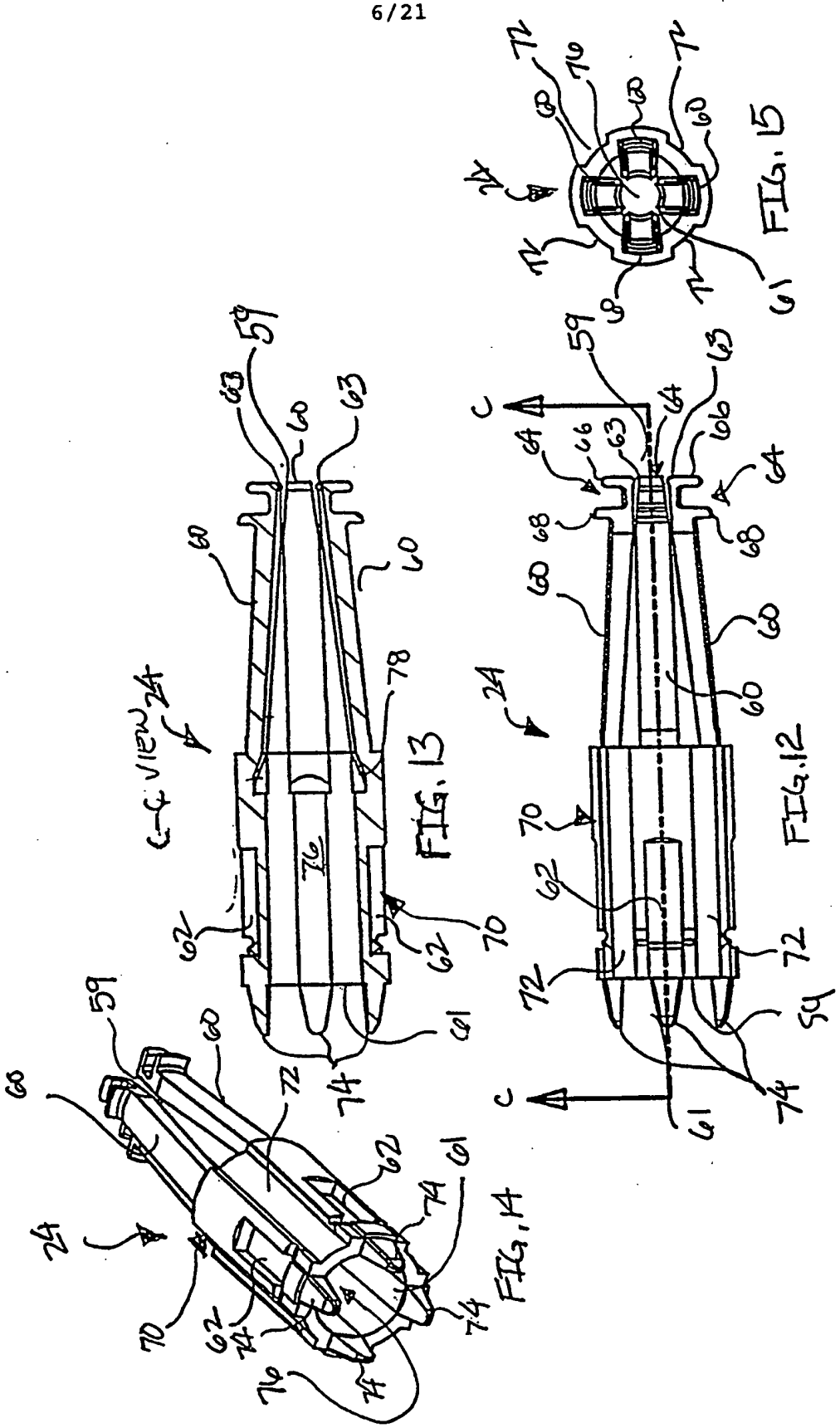


FIG. 15
FIG. 12
FIG. 13
FIG. 14
End View

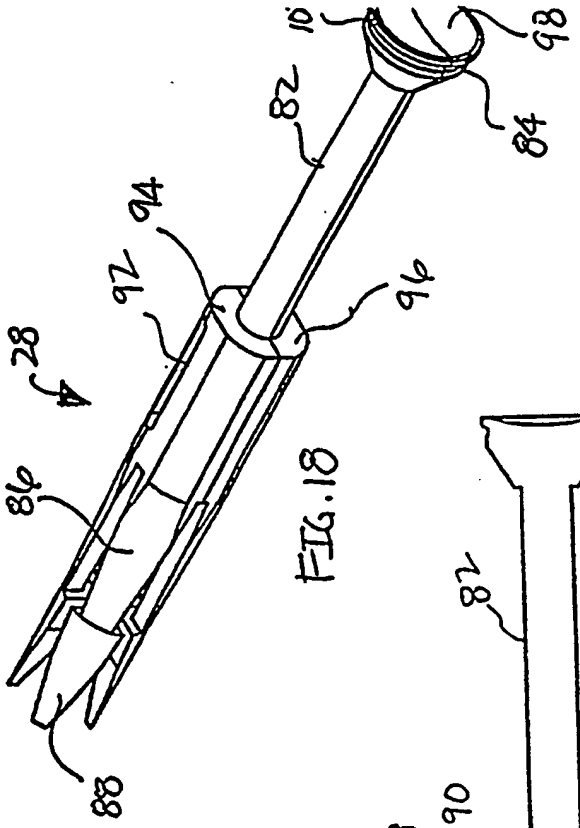


FIG. 18

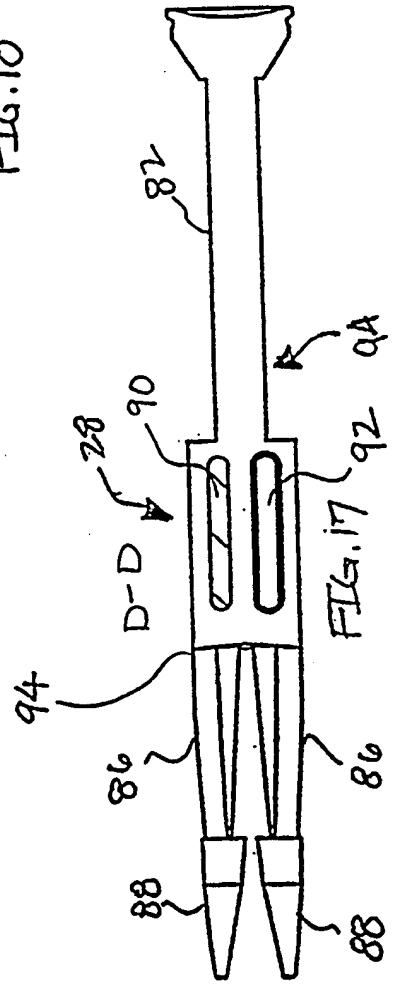


FIG. 17

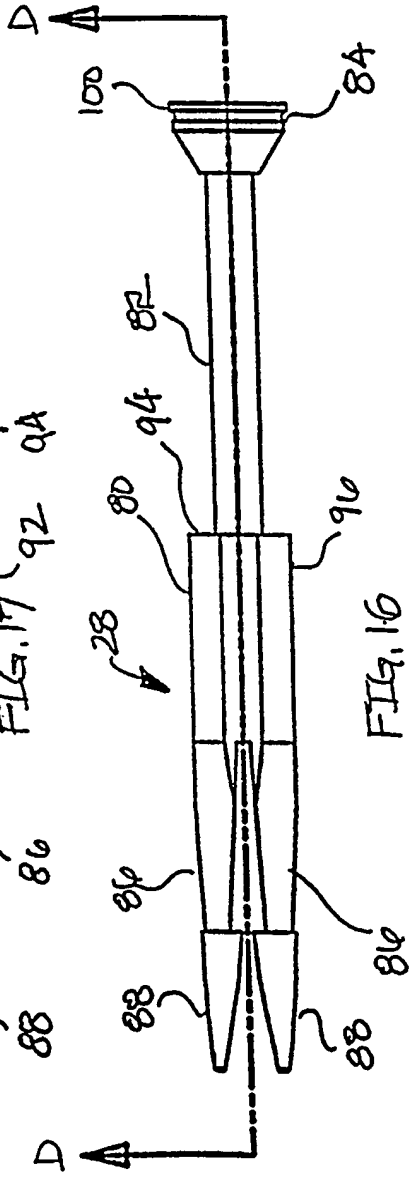


FIG. 16

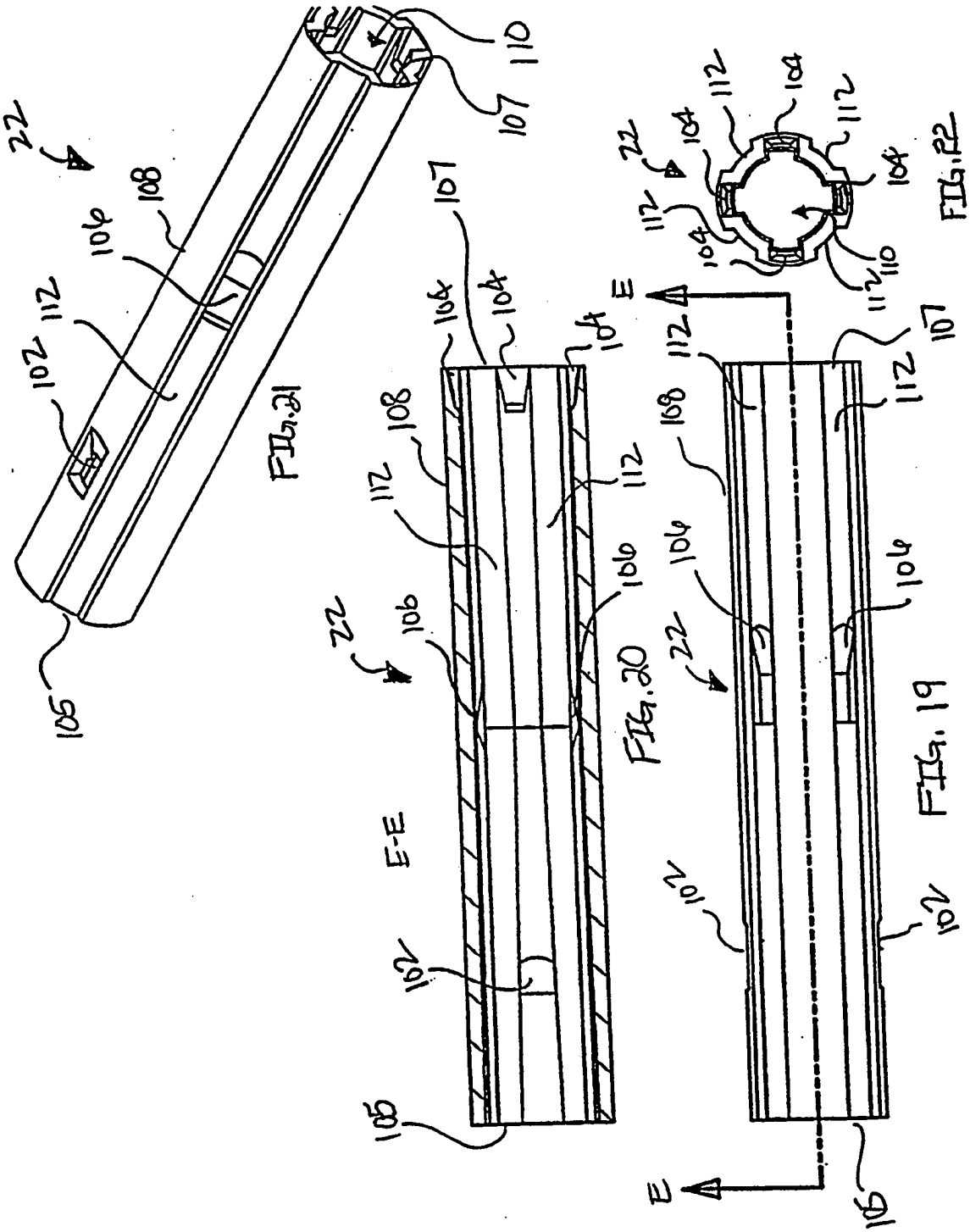


FIG.21 FIG.22 FIG.20 FIG.19

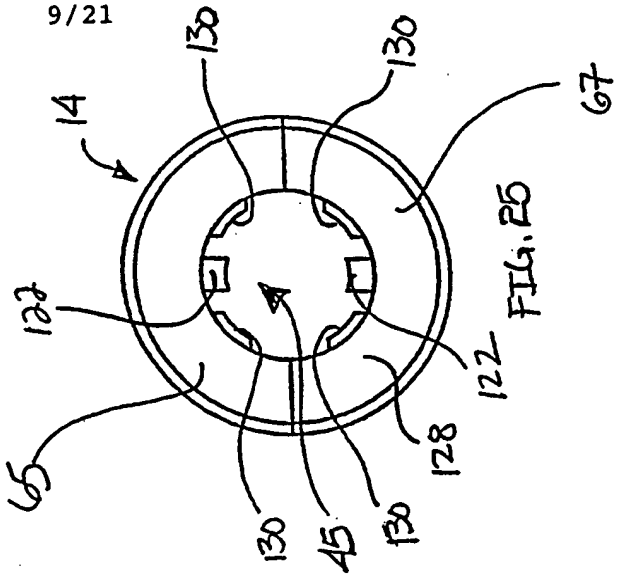


FIG. 25

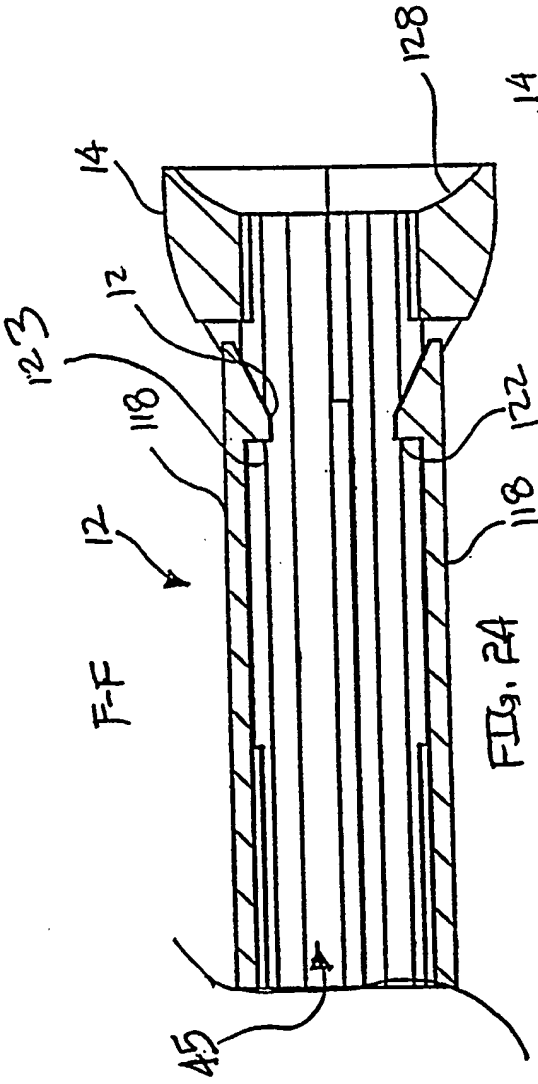


FIG. 24

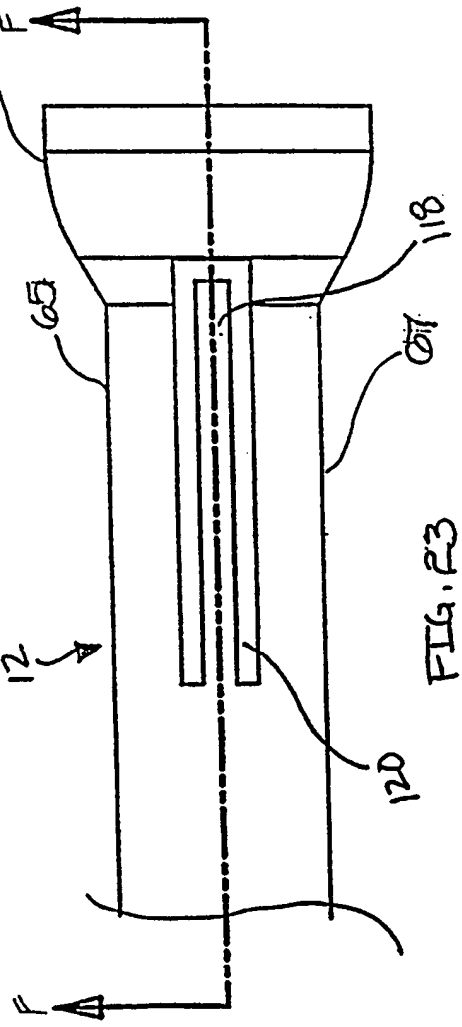


FIG. 23

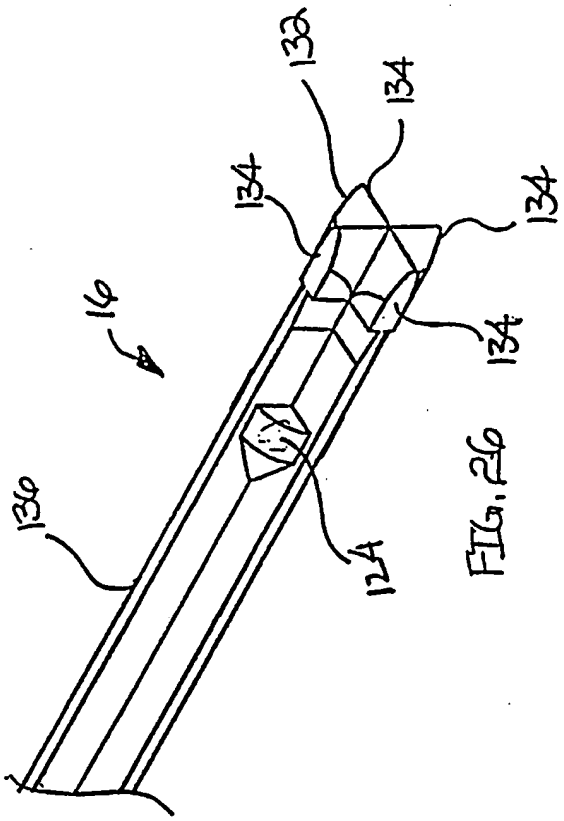


FIG. 26

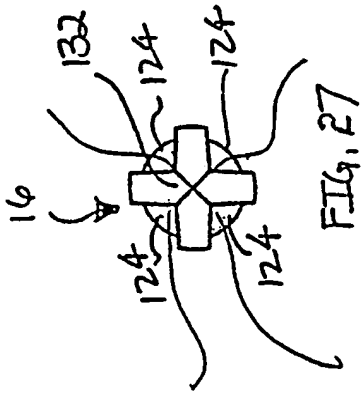


FIG. 27

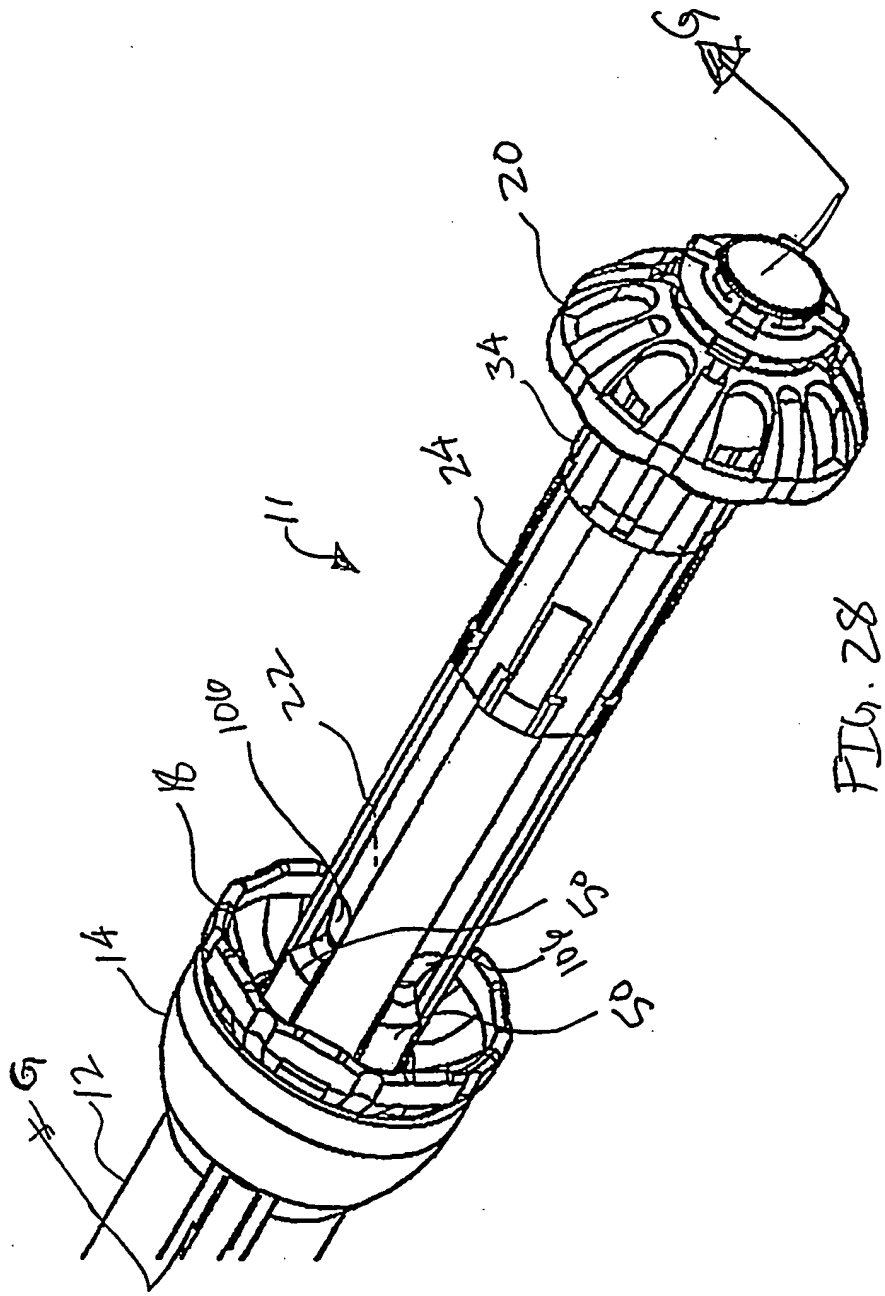


FIG. 2B

OPEN POSITION

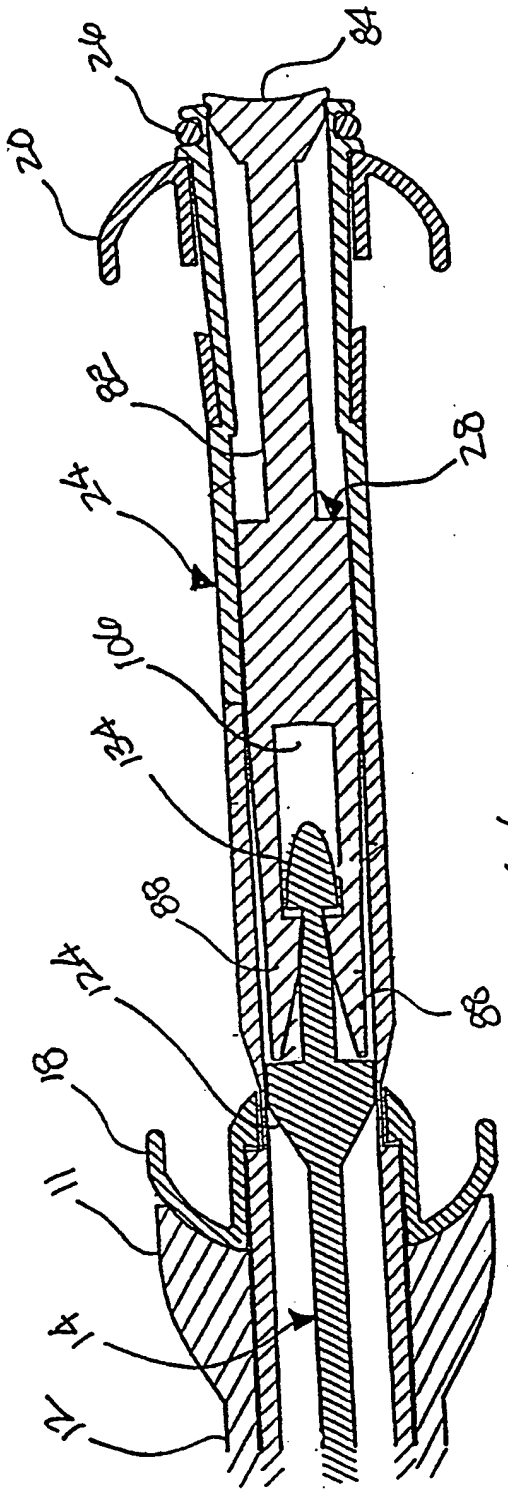


FIG. 29

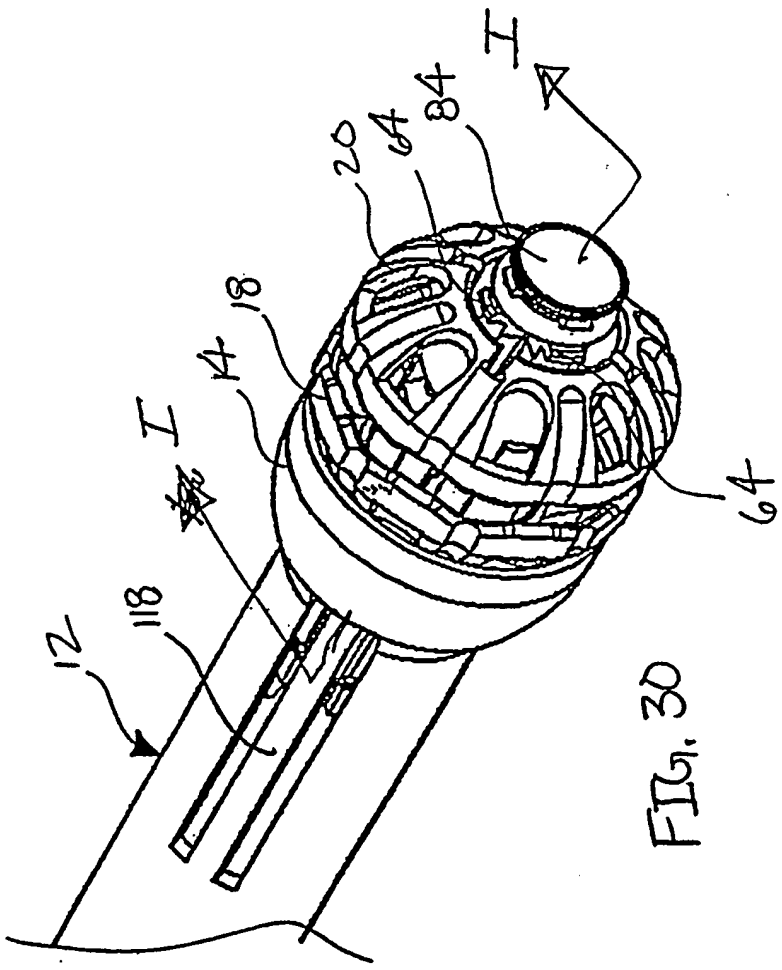


FIG. 3D

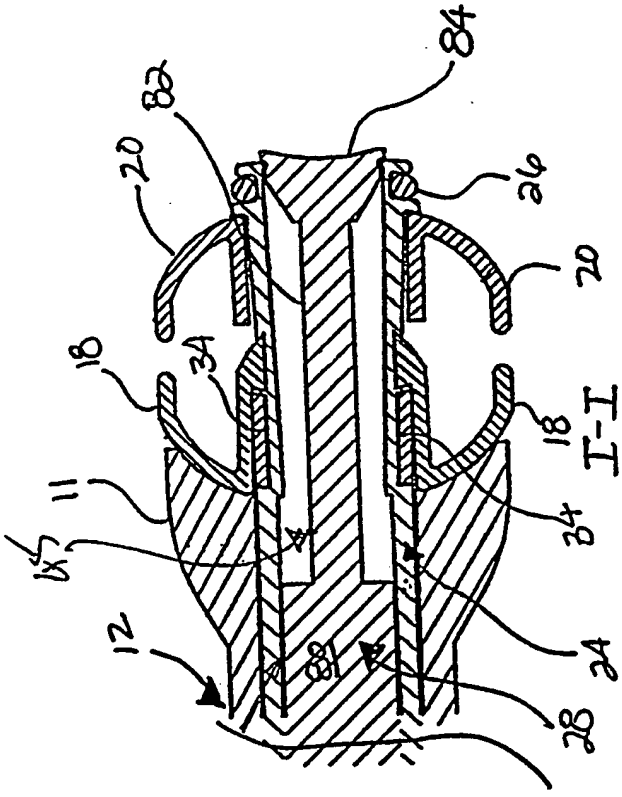
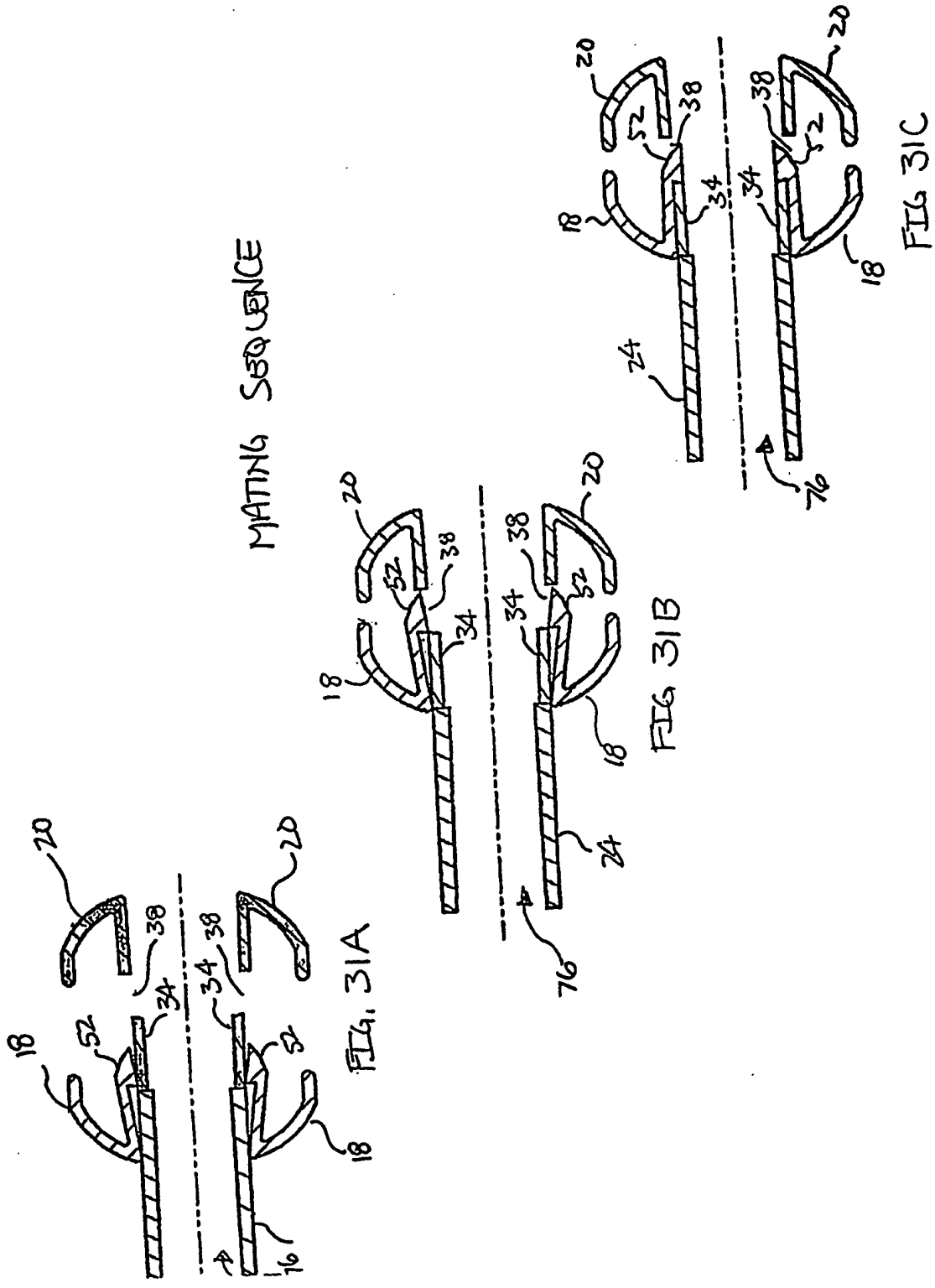


FIG. 3I

I-I


MATING SEQUENCE
FIG. 31A
FIG. 31B
FIG. 31C

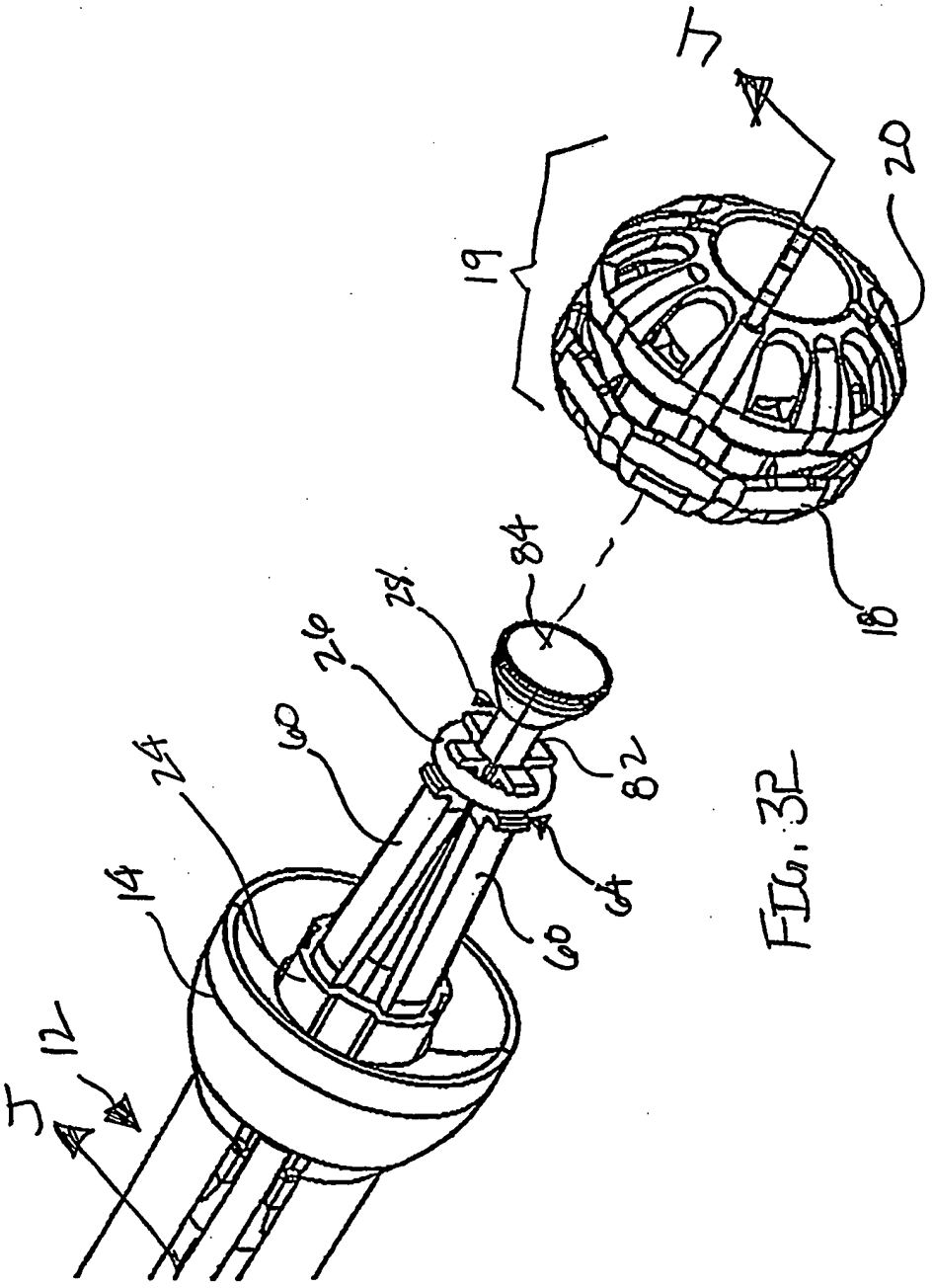
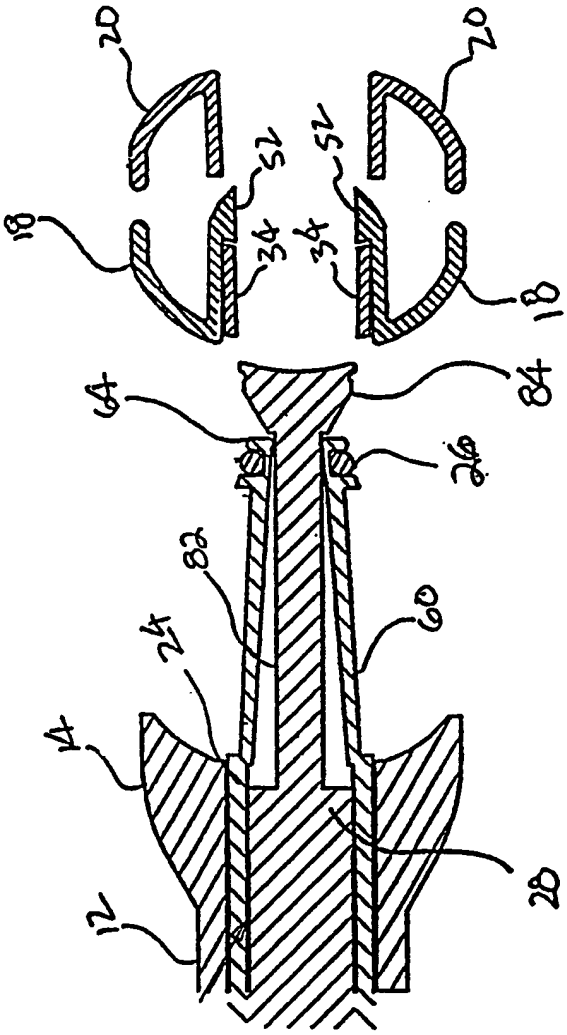


FIG. 32



J-J

FIG. 33

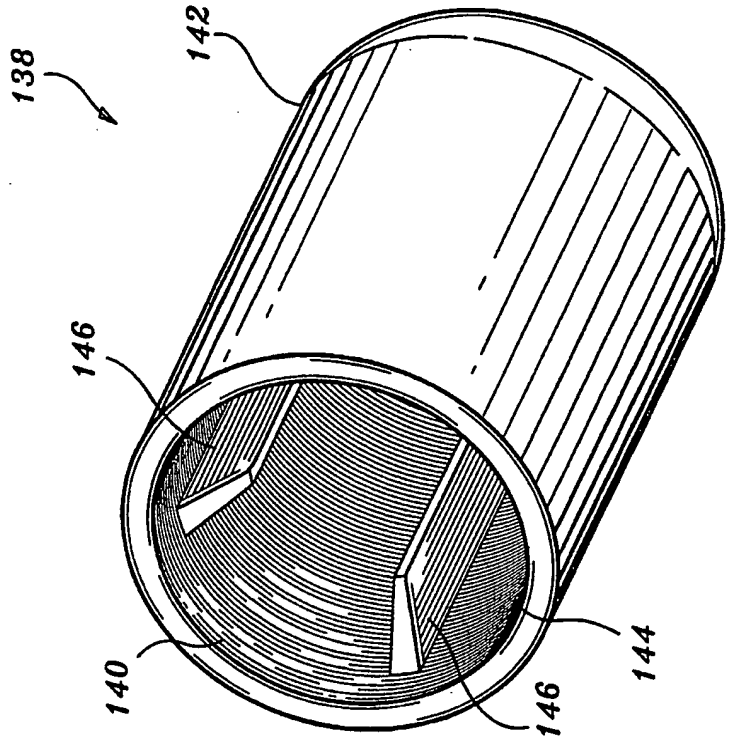


FIG. 34

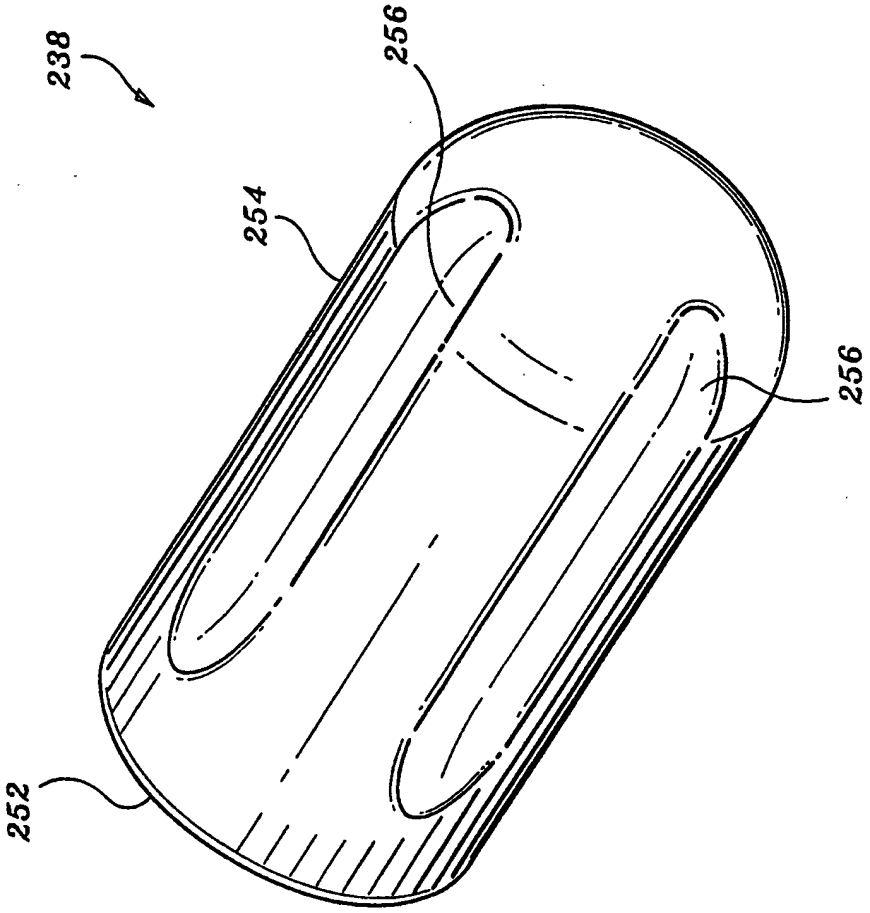


FIG. 35

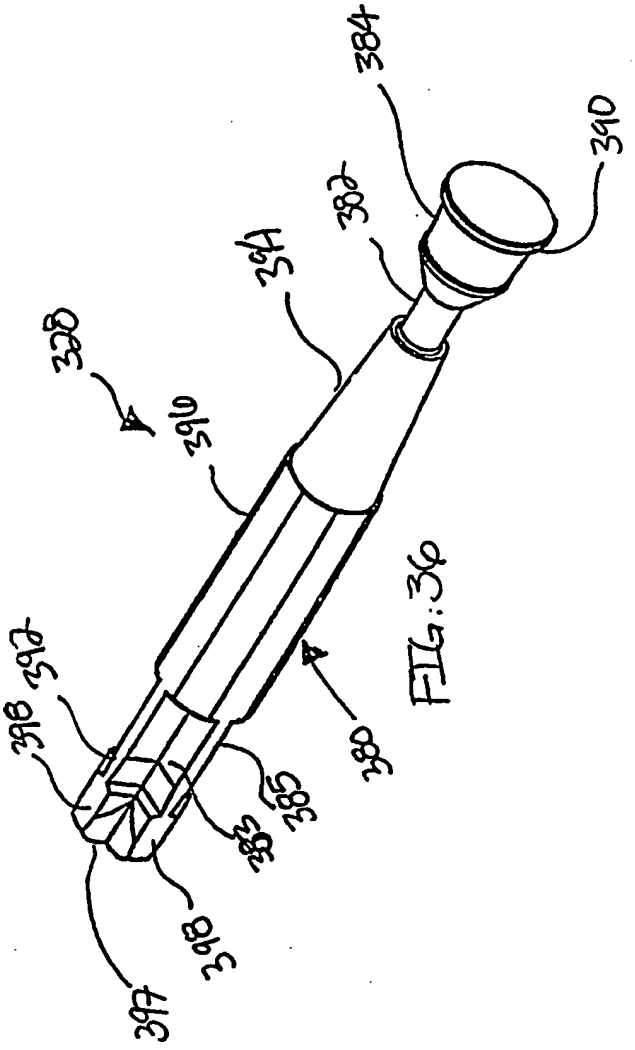

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FIG. 36

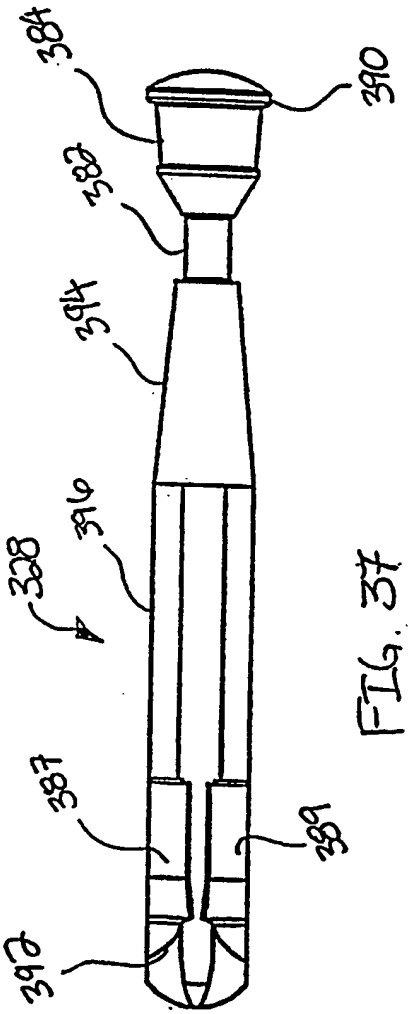
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FIG. 37

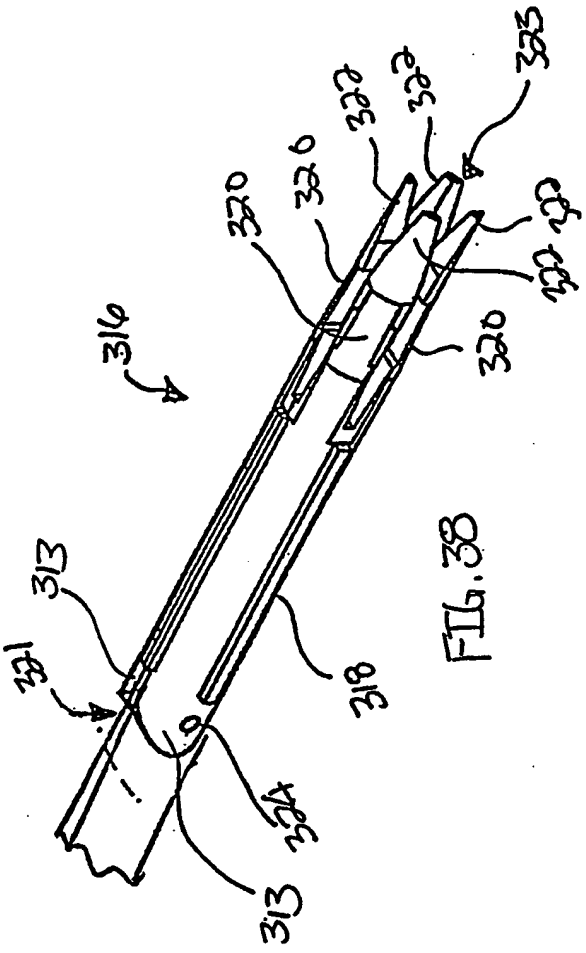

FIG. 38

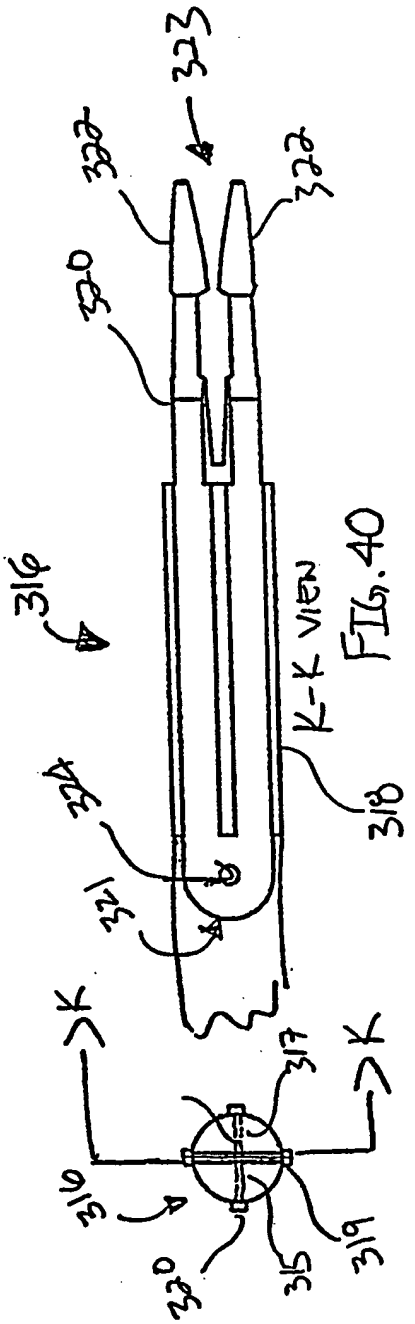

FIG. 40

FIG. 39

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/EP 98/06265

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 282 810 A (ALLEN ET AL.) 1 February 1994 cited in the application see the whole document	1-8,15, 25,26, 28,35,36
X	WO 81 00668 A (JANSEN) 19 March 1981 see page 8, line 12 - page 12, line 31; figures	1,4,6-8
A	EP 0 568 774 A (AMERICAN CYANAMID COMPANY) 10 November 1993 see abstract; claims; figures	1,35,36
A	EP 0 671 149 A (KOECKERLING ET AL.) 13 September 1995 see abstract; figures	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 January 1999	20/01/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Giménez Burgos, R

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

I. ...national application No.
PCT/EP 98/06265

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 37-41
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte onal Application No
PCT/EP 98/06265

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		AU 3682493 A	14-10-1993
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		DE 69305900 D	19-12-1996
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		US 5626591 A	06-05-1997